Supreme Court, U.S.
FILED
931431 MAR - 7 1994
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No.

IN THE

Supreme Court of the United States

OCTOBER TERM, 1993

MEDICAL ENGINEERING CORPORATION,
Petitioner,

v.

AMERICAN MEDICAL SYSTEMS, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

MARK T. BANNER
Counsel of Record
JERRY A. RIEDINGER
MARC S. COOPERMAN
A. BLAIR HUGHES
ALLEGRETTI & WITCOFF, LTD.
10 South Wacker Drive
Suite 3000
Chicago, Illinois 60606
(312) 715-1000
Counsel for Petitioner

March 7, 1994

Midwest Law Printing Co., Chicago 60611, (312) 321-0220

28 pp.

QUESTION PRESENTED

Section 287(a) of the Patent Law (35 U.S.C. § 287(a) (1988)), provides in pertinent part:

> Patentees, and persons making or selling any patented article for or under them, may give notice to the public that the same is patented . . . by fixing thereon the word "patent" or the abbreviation "pat.", together with the number of the patent . . . . In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice. Filing of an action for infringement shall constitute such notice.

The question presented in this case is as follows:

Whether a patent holder who has "fail[ed] so to mark," by distributing a substantial number of unmarked articles to the public, may obtain damages for infringement only from the time that "the infringer was notified of the infringement and continued to infringe thereafter," as the district court held, or whether that patent holder may obtain damages before "the infringer was notified of the infringement," simply by marking subsequently distributed articles with its patent number, as the Federal Circuit held.

RULE 29.1 LISTING

Medical Engineering Corporation is a wholly owned subsidiary of Bristol-Myers Squibb Company.

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On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

Medical Engineering Corporation respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals is reported at 6 F.3d 1523, and is reprinted in the appendix to this petition at App. 1 - App 36. The opinion of the United States District Court for the Eastern District of Wisconsin is reported at 794 F. Supp. 1370, and is reprinted in the appendix to this petition at App. 37 - App. 116.

JURISDICTION

The judgment of the court of appeals was rendered on October 4, 1993. That court denied a timely Petition for Rehearing and Suggestion for Rehearing In Banc on December 6, 1993, and is reprinted in the appendix to this petition at App. 117. The jurisdiction of this Court is based on 28 U.S.C. § 1254(1) (1988).

STATUTE INVOLVED

35 U.S.C. § 287(a) provides:

> Patentees, and persons making or selling any patented article for or under them, may give notice to the public that the same is patented, either by fixing thereon the word "patent" or the abbreviation "pat.", together with the number of the patent, or when, from the character of the article, this cannot be done, by fixing to it, or to the package wherein one or more of them is contained, a label containing a like notice. In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice. Filing of an action for infringement shall constitute such notice.

STATEMENT OF THE CASE

For purposes of this petition, no facts are disputed. Respondent, American Medical Systems, Inc. (AMS), owns the patent in suit, U.S. Patent No. 4,597,765 ('765 patent). It issued on July 1, 1986. AMS shipped its patented products without marking its patent number on them at least

until October 15, 1986. During that time it publicly distributed 1,939 products without a patent number. AMS did not even begin the internal process for marking its patent number on its products until two months after the patent issued. (App. 83-85). Although AMS subsequently shipped some or all of its products with the patent number, AMS did not give petitioner, Medical Engineering Corporation (MEC), actual notice of infringement until the complaint was filed. (App. 86).

On October 28, 1987, AMS sued MEC for patent infringement. MEC asserted that any damages that AMS might be awarded must be limited under the notice provision of the patent statute (35 U.S.C. § 287(a)), because of AMS' failure to mark the '765 patent number on the 1,939 products it distributed to the public for at least three and a half months after the patent issued. (App. 81, 84).

The district court ruled that, because of AMS' failure to mark substantially all of its patented products, "AMS plainly did not comply with the patent marking statute." (App. 85). The district court determined that AMS' failure to mark was not *de minimis*. (App. 24, 85). Between the patent's issuance and the time the lawsuit was filed, fully twenty-five percent of the products shipped did not have the patent number marked on them. (App. 85). The district court found that in the first six months of the patent's existence, 1,939 of the 3,320 total products shipped lacked any patent marking (App. 85), meaning nearly sixty percent failed to comply with the marking requirement.

Because AMS failed to mark its patent number on substantially all of its products, and because AMS deliberately refused to notify MEC of its contention of infringement before suing, the district court held Section 287(a) precluded AMS recovering damages for any infringement that occurred before it filed the present action. (App. 86-87).

On appeal, the Federal Circuit recognized that AMS shipped a significant number of patented products without marking. (App. 24). However, the Federal Circuit disagreed with the district court about the effect of AMS' failure to mark, and reversed the judgment regarding Section 287(a).

The Federal Circuit reasoned that the cases requiring marking of substantially all patented products were decided under the predecessor statutes to Section 287(a) and, therefore, were not controlling on the interpretation of the present statute. (App. 29).[1] Furthermore, according to the Federal Circuit, the language of Section 287(a) does not provide any time limit by which marking must begin. (App. 30). The Federal Circuit concluded that allowing recovery of damages from the time the shipment of marked products begins furthers the policy of encouraging marking—even if initial marking is delayed—because the sooner one complies with the marking requirements, the more likely one is to maximize the period for recoverable damages. (App. 30). Based on this analysis, the Federal Circuit held that Section 287(a) precludes recovery of damages only for infringement that occurred before the patentee stopped distributing products lacking the patent marking. (App. 31).

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[1] At least two of these cases were decisions by this Court: *Providence Rubber Co. v. Goodyear*, 9 Wall. (76 U.S.) 788, 801 (1870), cited in footnote 15 of the Federal Circuit opinion (App. 28), and *Wine Ry. Appliance Co. v. Enterprise Ry. Equip. Co.*, 297 U.S. 387, 394 (1936). These cases are discussed below.

REASONS FOR GRANTING THE WRIT

This case presents a straightforward and important question regarding the obligation of patent holders to provide notice of their patents to the public by marking their patent numbers on patented goods. Section 287(a) of Title 35 provides that, if a patent holder fails to mark its patented goods, "no damages shall be recovered by the patentee in any action for infringement" except after giving actual notice of the infringement to the infringer; that is, by accusing the infringer of infringement. The court of appeals below, however, held that even though a patent holder failed to mark its patent number on a significant number of patented goods distributed to the public for several months, it nonetheless could obtain damages for infringement of the patent—without accusing the infringer—simply by marking its subsequently distributed goods. In the court's view, the patent holder's penalty for failing to mark its goods was not a complete forfeiture of damages (absent a charge of infringement to the infringer) but simply a limitation of damages to the period after marking had begun.

This decision merits review for several reasons. First, the Federal Circuit has simply misread the language of Section 287(a). It is undisputed in this case that respondent "fail[ed] to mark" its products for several months, thus putting into public circulation numerous unmarked (though patented) products. According to the express terms of the statute, the penalty paid for that failure to mark is that the patent holder may recover "no damages . . . in any action for infringement" unless it then charges an infringer with infringement. Put another way, the right to recover damages *based on marking* is lost once a substantial number of unmarked products has been distributed to the public. The contrary reading by the appellate

court below—that a right to damages can be created by belated marking—is contrary to the plain meaning of the statutory language.

The decision below is also contrary to the central purpose of Section 287(a): to discourage distribution to the public of unmarked, but patented goods. To the extent that goods in commerce are unmarked, "[t]he public may rely upon the lack of notice in exploiting shapes and designs accessible to all." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 162 (1989). But, if a patent holder may distribute the same product in both marked and unmarked form—with only the limited penalty required by the Federal Circuit—then the public cannot know with any certainty whether a particular product is public property and subject to lawful copying, or is merely an unmarked version of a product protected by a patent, and therefore private property. Elimination of just that uncertainty caused by a failure to fully and consistently mark is the reason Section 287(a) allows damages only upon the giving of actual notice of infringement of the patent.

The proper resolution of this issue is of considerable importance to patent holders, to possible infringers, and to the public. Because it affects every article subject to marking, the holding below necessarily establishes the critical balance between the need for disclosure of patents to the public, and the protection given to patent holders by the patent laws. In our view, the decision sets that balance in the wrong place. Furthermore, given that the Federal Circuit is the court ultimately charged with overseeing application of the patent laws, including the rights of patent holders to collect damages from infringers of their patents, its judgments in this area carry exceptional weight. Review by this Court is necessary to ensure that

Section 287(a) is applied as it is written and as Congress intended.

I. The Federal Circuit's Interpretation of 35 U.S.C. § 287(a) Conflicts With the Plain Language of the Statute

The decision in this case turns on the construction of Section 287(a) of the Patent Laws. That section provides that patent holders "may give notice to the public" that goods are patented by marking them with a patent number as provided in the statute. It then goes on to state (emphasis added):

> In the event of failure so to mark, *no* damages shall be recovered by the patentee in *any* action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice.

There is no dispute here that there was a failure to mark by respondent. From the time the patent issued, respondent publicly distributed nearly 2000 patented goods without a patent number. The sole issue, therefore, is what the consequence of that failure to mark must be. Rejecting petitioner's argument that respondent can collect no damages for infringement prior to the time it accused petitioner of infringement, the Federal Circuit reversed the district court and held that respondent was barred from obtaining damages only for acts that occurred during the period of the failure to mark. Thus, according to the court's reading, marking of its subsequently distributed products entitled respondent to damages from that point forward, regardless of whether the infringer was actually accused of infringement.

This reading of Section 287(a), however, is directly contrary to its language. The starting point for interpreting a statute is, of course, the language of the statute itself. *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980). The better reading, indeed the plain reading of the statute, is that it means just what it says: that once a failure to mark has occurred, "no damages" shall be recovered "in any action" for infringement, except on proof that the infringer was "notified of the infringement."[2]

The statute works simply. Congress has made the determination that if a patent owner fails to advise the public that its goods are patented by marking the patent number on those goods, the patent owner is penalized by recovering *no* damages in *any* action for infringement. The only exception to this penalty provided by Congress is if the patent owner proves "that the infringer was notified of the infringement and continued to infringe thereafter."

The Federal Circuit simply wrote into the statute a second exception to the penalty for those circumstances, here present, where there was an admitted "failure so to mark" of a substantial number of products, followed by marking of later distributed products. Rather than apply the language of Section 287(a) as written, the Federal Circuit "construe[d] section 287(a) to preclude recovery of damages only for infringement for any time prior to compliance with the marking or actual notice requirements of the statute." (App. 31). In effect, therefore, the court treated the statute as if it provided that:

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[2] The Federal Circuit agreed with the district court's finding that petitioner was not notified of infringement until respondent filed the complaint. (App. 31-32).

> In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice, *or except on proof that the patentee marked its subsequently distributed products with its patent number, in which event damages may be recovered only for infringement occurring after such marking.*

But, if Congress had intended to make marking of subsequently distributed goods by the patentee an exception to the damages limitation of Section 287(a), it could easily have done so with an explicit statement as it did with respect to the actual notice exception. This Court should not conclude that Congress' failure to include this additional exception was unintentional, and permit the addition of an implied exception. *See Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 109 (1980) ("We are consequently reluctant to conclude that Congress' failure to include FOIA requests within the exceptions to § 6(b)(1) listed in § 6(b)(2) was unintentional.").[3]

There was a "failure so to mark." That event having occurred, the plain language of the statute should be ap-

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[3] *See also Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 456 (1984) ("[I]t is not our job to apply laws that have not yet been written."); *United States v. Rutherford*, 442 U.S. 544, 555 (1979) ("Under our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy."); *United States v. Great N. Ry. Co.*, 343 U.S. 562, 575 (1952) ("It is our judicial function to apply statutes on the basis of what Congress has written, not what Congress might have written.").

plied. That language dictates that "no damages" should be recovered "in any action" for infringement occurring prior to the filing of a complaint, except on proof that the infringer was "notified of the infringement."

II. The Federal Circuit's Interpretation of 35 U.S.C. § 287(a) Is Inconsistent with the Policies Underlying the Patent Laws, Including those Outlined by This Court in its Precedent

The federal patent laws delineate the boundaries between public and private property. Not only do the laws define what is patentable, and thus subject to becoming private intellectual property, they designate and protect what intellectual property is *not* safeguarded by patent, and thus free for the public to use. This Court repeatedly has affirmed the important pubic policy served by the patent laws in differentiating between ideas subject to patent protection and those freely available. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51, 156, 159-62 (1989); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262, 264 (1979); *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480-81 (1974); *Lear, Inc. v. Adkins*, 395 U.S. 653, 656, 668-70 (1969); *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230-31 (1964); *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234, 247 (1964).

The Court has explained that "implicit in the Patent Clause itself" is the concept "that free exploitation of ideas will be the rule, to which the protection of a federal patent is the exception." *Bonito Boats*, 489 U.S. at 151. Notably, however, Congress and the Court have recognized that "in rewarding useful invention, the 'rights and welfare of the community must be fairly dealt with and effectually guarded.' " *Sears*, 376 U.S. at 230 (quoting *Kendall v. Winsor*, 21 How. (62 U.S.) 322, 329 (1859)). Thus,

"[f]rom their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy." *Bonito Boats*, 489 U.S. at 146. Significantly, the Court has affirmed that public competition in freely available *unpatented* ideas is an essential component of the "bargain" embodied in the federal patent laws:

> The attractiveness of such a bargain, and its effectiveness in inducing creative effort and disclosure of the results of that effort, depend almost entirely on a backdrop of free competition in the exploitation of unpatented designs and innovations.

Bonito Boats, 489 U.S. at 151. Simply put, the patent laws reflect a "strong federal policy favoring free competition in ideas which do not merit patent protection." *Lear*, 395 U.S. at 656.

Notice to the public of what ideas are protected by patent is an essential part of drawing the line between ideas that are freely available to the public, and those that are not in the public domain because of a government grant of exclusive rights. The requirements of the marking statute provide that necessary notice. Recently in *Bonito Boats*, 489 U.S. at 162 (citation omitted), this Court wrote about the statute at issue here:

> The notice [marking] requirement is designed "for the information of the public," and provides a ready means of discerning the status of the intellectual property embodied in an article of manufacture or design. The public may rely upon

> the lack of notice [marking] in exploiting shapes and designs accessible to all.[4]

The leading treatise on patent law explains this policy further:

> The statute strikes a delicate balance between the rights of the patent owner, the public, and the accused infringer. The damage limitation as to failure to mark serves the public interest in not being deceived by the appearance of unmarked (and hence apparently copyable) products. *The accused infringer is given standing to enforce that public interest by avoiding damage liability* (until specific notice is given, which changes the equities).

5 DONALD S. CHISUM, PATENTS § 20.03[7][c][vi] n. 133 (1993) (emphasis added) (citation omitted).

The Court has consistently recognized that to carry out these purposes of informing the public, and preventing the public from being deceived, substantially all products must be marked, not just "some" products. In *Providence Rubber Co. v. Goodyear*, 9 Wall. (76 U.S.) 788, 801 (1870) (quoting Act of March 2, 1861, ch. LXXXVIII, § 13, 12 Stat. 249 (1863)), the Court noted the requirement that "every article" be marked. In *Dunlap v. Schofield*, 152

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[4] It should be noted that in *Bonito Boats*, this Court referred to the marking portion of the statute as the "notice" requirement. That is, the requirement to give "notice" to the world of the patent by marking products with the patent number. This is different from the portion of Section 287(a) that addresses whether the infringer was "notified of the infringement" and permitting recovery of damages only after such "notice." This latter language deals with charging infringement—something which did not occur in the present case until respondent filed the complaint. (*See supra* note 2). For clarity, when the marking portion of the statute is referred to, it will be specifically noted.

U.S. 244, 247-48 (1894) (construing Act of July 8, 1870, ch. CCXXX, § 38, 16 Stat. 203 (1871)) (emphasis added), the Court said:

> [T]he patentee or his assignee . . . cannot recover damages against infringers of the patent, unless he has given notice of his right, either to the *whole public* by marking his article "Patented" or to the particular defendant by informing them of his patent, and of their infringement.

In *Wine Ry. Appliance Co. v. Enterprise Ry. Equip. Co.*, 297 U.S. 387, 393 (1936) (construing Act of July 8, 1870, ch. CCXXX, § 38, 16 Stat. 203 (1871)) (emphasis added), this Court again commented on the comprehensive nature of the marking provision:

> *[W]henever a patented article is made or vended* . . . it becomes [the patentee's] duty to give sufficient notice to the public "that the same is patented" either by placing thereon or upon the label the word "Patented."

Regarding the current marking statute, this Court stated in *Bonito Boats*, 489 U.S. at 161 (emphasis added):

> The federal patent scheme provides a basis for the public to ascertain the status of the intellectual property embodied in *any article in general circulation.*

Thus, by requiring the marking of substantially all patented articles, the marking statute is designed to protect the public by minimizing the possibility that the public might innocently believe a patented article can be copied. The incentive to mark is created by allowing an accused infringer to stand in the shoes of the public and enforce the public interest in not being deceived by unmarked goods, even if the accused infringer knows of the patent. 5 CHISUM, *supra* at n. 133.

This is exactly what happened in the present case. Petitioner introduced its product to the market, unaware of the existence of a pending patent application because respondent did not put "patent pending" on its own commercial product. (App. 7). After the patent issued, respondent failed to mark substantially all of its patented products, introducing into the public domain a significant number of unmarked products that were (by then) patented. Furthermore, having failed to mark, respondent deliberately refused to charge petitioner with infringement, which would have halted the "penalty" of the marking statute, because, as the district court found, respondent "felt it advantageous to withhold making an explicit accusation of infringement to prevent a declaratory judgment suit from being filed." (App. 86). The Federal Circuit held that this failure to mark did not bar the respondent from obtaining damages for infringement prior to accusing petitioner of infringement; reasoning that a patent owner can begin to collect damages once marking is "substantially consistent and continuous." (App. 31).

The Federal Circuit's conclusion creates an unjustified inconsistency. There is no dispute that a patent owner that distributes twenty-five percent of its products unmarked *cannot* recover damages if the unmarked products were distributed *throughout the entire period of distribution*, while marked products were being distributed at the same time.[5] Yet, according to the Federal Circuit, a patent owner that distributes twenty-five percent of its products unmarked *can* recover damages if the unmarked

[5] The Federal Circuit recognized this. "[Respondent] was not in full compliance with the marking statute while it continued to ship its unmarked products, which contained to mislead the public into thinking the product was freely available." (App. 32-33).

products were all distributed *at the beginning of the period of distribution*. In either case, however, the harm to the public is the same: twenty-five percent of the purchasers have been mislead. In either case, the public cannot rely on the required patent marking as a reliable indication of where the border lies between patented (hence private) property and unpatented (hence public) property. Nothing in the statute suggests this curious outcome was within Congress' intent.

The result also conflicts with this Court's reasoning underlying its decision in *Bonito Boats*.[6] There, the Court struck down a Florida statute protecting unpatented ideas as being inconsistent with federal patent law. In contrast to the federal patent scheme where the public may "ascertain the status of the intellectual property embodied in any article in general circulation" through the marking statute, the Florida scheme rendered "the status of the design and utilitarian 'ideas' embodied in the boat hulls it protects uncertain." *Bonito Boats*, 489 U.S. at 161-62. The Court concluded that "[t]he Florida scheme blurs this clear federal demarcation between public and private property," established in this Court's precedent and the patent laws. *Bonito Boats*, 489 U.S. at 162.

Like the Florida statute in *Bonito Boats*, the Federal Circuit's interpretation of the marking provision of the

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[6] At issue in *Bonito Boats* was a Florida statute protecting the designs of molded boat hulls. Protection was offered under the statute for designs that had been freely circulated to the consuming public. 489 U.S. at 159. Petitioner there sued a competitor claiming the competitive design violated the Florida statute. 489 U.S. at 144-45. This Court affirmed the Florida Supreme Court's decision striking down the Florida law as inconsistent with the policies embraced by the federal patent statute. *Bonito Boats*, 489 U.S. at 157.

patent statute blurs Congress' demarcation between public and private property. In effect it has taken the nearly 1,300,000 existing U.S. patents[7]—each a form of legalized "private monopoly"—and turned them into hidden "mines" floating in the sea of ideas embodied in goods in public distribution. The public can no longer sail in that sea confident that the water is safe where no mine has been marked. The ruling of the Federal Circuit will improperly impede the use of ideas in public circulation by removing a clear demarcation between ideas in the public domain and those subject to the private rights of patent owners. *See Bonito Boats*, 489 U.S. at 157 ("We believe that the Florida statute at issue so substantially impedes the public use of the otherwise unprotected design and utilitarian ideas embodied in unpatented boat hulls as to run afoul to the teaching of our decisions in *Sears* and *Compco*.").

Not only do the results of the Federal Circuit's decision run afoul of the law, the court's reasoning in reaching its decision is misguided. The stated rationale behind the Federal Circuit's decision was to provide incentive to the patentee to mark its products with its patent number. The Federal Circuit reasoned that if a patent owner is prevented from getting damages because of a failure to mark its patent number on its products, a patentee who fails to initially mark its products has no incentive to mark its subsequently shipped products. Thus, in order to create an incentive to begin marking, the panel interpreted the statute to enable a patentee who commences marking to

[7] Nearly 1,300,000 patents have been issued by the United States Patent and Trademark Office during the last seventeen years (the term of a patent).

recover damages from the date on which the patentee begins fully complying with the statute. (App. 30).

The decision wrongly assumes that damages for infringement is the only incentive a patentee has to mark its products. Contrary to the Federal Circuit's reasoning, a patentee *always* has incentive to mark its products with its patent number. The patentee benefits from notifying the world that its products are patented, even if it does so belatedly. That notice sends a powerful business and sales message. Notice of the patent informs the public, including competitors and customers, that no one else has the right to make that product, and that the ideas embodied in the product are *not* available for the public to exploit. Marking products with the patent number serves to deter potential infringers, and potential competitors, as well as to avoid unnecessary litigation. Thus, even the patentee who initially fails to mark has an ongoing, continuing, and never-ending incentive to commence marking—throughout the entire seventeen year term of the patent.

Indeed, greater incentive to mark would result from applying Section 287(a) as written, as done by the district court. When a patent owner knows that a failure to mark can severely limit damages, strong efforts will be undertaken to mark as soon as possible. Under the approach of the Federal Circuit, patent owners need not concern themselves with marking immediately, since they can always initiate their right to damages by belatedly marking, even if that marking starts years after the patented products were first sold. Few patent owners will indulge in efforts to immediately mark if there is little or no penalty for failing to do so.

Without a doubt, the patentee who fails to initially mark its patent number on more than a *de minimis*[8] amount of product is penalized. The penalty, established by Congress, is that the patentee must provide actual notice of infringement to the infringer before it has the right to obtain damages for infringement. That penalty provides incentive for patentee's to place the proper marking on substantially all of their products, and thus allows the public to determine the availability of ideas embodied in the products. In addition, that penalty serves to protect the public from the patentee who delays marking and deliberately delays providing actual notice of infringement, like respondent did in this case. The penalty is not harsh, however, because the patent holder can always start the damages clock running merely by charging infringement, a task that can be accomplished with a single paragraph letter or even a phone call.[9] *See Wine Ry. Appliance Co. v. Enterprise Ry. Equip. Co.*, 297 U.S. 387, 398 (1936) (The marking statute "provides protection against deception and requires nothing unreasonable of patentees.").

In summary, the Federal Circuit's decision marks a significant departure from Supreme Court precedent. This new course is at odds with the strong federal policy of

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[8] Section 287(a) has been interpreted to allow a patent owner a *de minimis* number of goods to be shipped unmarked as the patent owner readies the marking process. *See* 5 D. CHISUM, PATENTS, § 20.03[7][c][iii] n. 109. The courts below agreed that respondent shipped more than a *de minimis* number of unmarked goods. (App. 24, 85).

[9] Furthermore, even if a patent holder fails to mark, and does not charge infringement so the damages limitation of Section 287(a) is in full effect, the patent owner may still obtain an injunction and damages against an infringer for infringement occurring after a complaint is filed.

protecting the public's right to use freely circulated *unpatented* ideas, by causing uncertainty in the availability of ideas embodied in publicly circulated items. *See Bonito Boats*, 489 U.S. at 163. The decision is likely to result in the public being mislead into thinking patented products are freely available. The decision will substantially impede the public use of otherwise unprotected ideas embodied in items in public circulation. These results run afoul of this Court's precedent and should not be allowed to stand.

III. The Federal Circuit's Decision Addresses an Issue of National Importance

This is not a case where the court's decision below will affect only the litigants, or a small class of persons. The Federal Circuit's decision will affect the entire public, because the court was interpreting a statute "designed 'for the information of the public.' " *Bonito Boats*, 489 U.S. at 162. Each of the nearly 1,300,000 patents issued during the last seventeen years affect every business and every citizen in the United States. Under the Federal Circuit's decision, each can be an unmarked mine waiting to detonate.

Every day the public is surrounded by newly developed products and technology. Improvements in these products and technology are spurred by the public's exposure to what exists today. The ideas embodied in these items "are the tools of creation available to all." *Bonito Boats*, 489 U.S. at 156. The public has a right to know when goods are thrust into commerce containing ideas not "available to all," and the marking statute is the primary vehicle to provide that public knowledge. By eviscerating the penalty designed by Congress for failure to mark, the

Federal Circuit decision has eliminated the ability of the public to rely on a lack of patent marking in choosing whether to use ideas that appear to be in the public domain. Innovation is likely to be deterred because of this uncertainty.

Furthermore, the decision of the Federal Circuit will have implications for the public far beyond the confines of this case because of the nature of the Federal Circuit Court of Appeals itself. The Federal Circuit sits as the *sole* intermediate appellate court in patent cases. Therefore, by definition, there can be no "conflict" among decisions of courts of appeal in patent cases warranting certiorari from this Court. However, as this Court has recognized, because the Federal Circuit has exclusive jurisdiction over appeals from all United States District Courts in patent litigation, the rules it applies in those cases are matters of special importance to the entire Nation. *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 113 S. Ct. 1967, 1971 (1993).

CONCLUSION

For the reasons above, the petition for a writ of certiorari should be granted.

Respectfully submitted,

MARK T. BANNER
Counsel of Record
JERRY A. RIEDINGER
MARC S. COOPERMAN
A. BLAIR HUGHES
ALLEGRETTI & WITCOFF, LTD.
10 South Wacker Drive
Suite 3000
Chicago, Illinois 60606
(312) 715-1000
Counsel for Petitioner

March 7, 1994

Supreme Court, U.S.
FILED

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931431 MAR - 7 1994

No. OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1993

MEDICAL ENGINEERING CORPORATION,
Petitioner,

v.

AMERICAN MEDICAL SYSTEMS, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

APPENDIX TO THE PETITION FOR A WRIT OF CERTIORARI

MARK T. BANNER
Counsel of Record
JERRY A. RIEDINGER
MARC S. COOPERMAN
A. BLAIR HUGHES
ALLEGRETTI & WITCOFF, LTD.
10 South Wacker Drive
Suite 3000
Chicago, Illinois 60606
(312) 715-1000
Counsel for Petitioner

March 7, 1994

Midwest Law Printing Co., Chicago 60611, (312) 321-0220

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APPENDIX TO THE PETITION FOR A WRIT OF CERTIORARI

App. 1

Nos. 92-1538, 92-1555

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

AMERICAN MEDICAL SYSTEMS, INC.,

Plaintiff/Cross-Appellant,

v.

MEDICAL ENGINEERING CORPORATION,

Defendant-Appellant.

October 4, 1993

OPINION:

Before NIES, Chief Judge, MICHEL and RADER, Circuit Judges.

MICHEL, Circuit Judge.

American Medical Systems, Inc. (AMS)[1] brought suit in the United States District Court for the Eastern District of Wisconsin against Medical Engineering Corporation (MEC)[2] for willful infringement of United States Patent No. 4,597,765, issued to Klatt (the '765 patent).

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[1] AMS is a wholly-owned subsidiary of Pfizer, Inc.

[2] MEC was originally an independent company, but during the course of this litigation it became a wholly-owned subsidiary of Bristol-Myers Company (now Bristol-Myers Squibb Corporation) in 1982.

MEC counterclaimed for declaratory judgment of invalidity and noninfringement, for an alleged breach of warranty, and for intentional, negligent and fraudulent misrepresentation by AMS.

After a bench trial, the district court issued its Decision and Order, No. 87-C-1236(JPS),[3] on June 25, 1992, rejecting each of MEC's counterclaims and holding that the '765 patent was not invalid and was infringed. The court further found that MEC's infringement was willful and that AMS was entitled to an award of enhanced damages of 1.5 times its proven lost profits and reasonable royalties. The court limited AMS's recoverable damages to those incurred after the filing date of the lawsuit, however, due to AMS's initial failure to mark its patented articles under 35 U.S.C. § 287(a) (1988). On September 1, 1992, the district court entered judgment in accord with its decision and permanently enjoined MEC from any further infringement of the '765 patent.

On appeal, MEC concedes validity and infringement, but challenges the district court's finding of willfulness and its award of enhanced damages. MEC also argues error in the denial of its counterclaim for breach of warranty and additionally alleges a violation of its Seventh Amendment right to a jury trial.[4] AMS cross-appeals the district court's limitation of its recoverable damages under 35 U.S.C. § 287(a).

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[3] The district court opinion is reported at 794 F. Supp. 1370, 26 USPQ2d (BNA) 1081 (E.D. Wis. 1992).

[4] MEC does not appeal the district court's ruling on its misrepresentation counterclaims.

Because the district court's finding of willfulness is not clearly erroneous, we affirm the court's finding on this aspect. Because no abuse of discretion has been shown, we also affirm the court's enhancement of the actual damages by 1.5 times. Finding no error, we also affirm the district court's holding that there was no breach of warranty. Furthermore, we hold that MEC's alleged violation of its Seventh Amendment right to a jury trial is without merit. On AMS's cross-appeal, however, because the district court improperly construed 35 U.S.C. § 287(a) in limiting AMS's recoverable damages to those incurred after the suit was filed, we reverse and remand to the district court for a new determination of damages consistent with this decision.

BACKGROUND

1. History of Competition Between AMS and MEC

AMS and MEC were vigorous competitors in the area of penile prostheses.[5] Each company had its own commercial version of a fluid-filled prosthetic device. AMS's prosthesis was called the "Hydroflex" and MEC's equivalent device was the "Flexi-Flate." Both devices were initially sold unfilled in a "dry pack" configuration.

AMS and MEC were previously involved in two interference proceedings and one arbitration concerning this prosthesis technology. All of these prior actions were settled by agreement of the parties.

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[5] MEC states that it abandoned the penile prosthesis market in the summer of 1991.

One of the interference actions, Interference No. 100,779 (the '779 interference), was settled by an agreement known as the "Hakky agreement."[6] All of the counts of the '779 interference were directed solely to the prosthetic devices themselves.

The Hakky agreement contained a warranty provision which was set out in two paragraphs of the settlement agreement as follows:

> 17.7. AMS and MEC each represent that their respective current technical disclosures to each other are accurate and complete with respect to the patent issues in the '779 interference.
>
> 17.8. AMS and MEC each warrant that there are no other issued patents, nor any pending applications for letters patent, reissue, continuation, continuation-in-part, or divisions with respect to any device disclosed to the warranting party by the other party which would result in any infringement or other potential litigation issue.

The Hakky agreement was signed by both parties in March of 1985.[7] The disclosures made by both parties

---

[6] At trial, MEC also referred to the settlement agreement from the other interference, (the Finney agreement), and the arbitration agreement between the parties. MEC's arguments on appeal do not rely on these agreements; accordingly, these agreements will not be addressed further.

[7] The application for the '765 patent was pending at the time this agreement was signed by the parties. The '765 patent is

(continued...)

pursuant to the Hakky agreement were limited to technology involving the actual devices. At the time of this agreement, neither party discussed nor implicated matters beyond the actual devices themselves, such as the concept of pre-filling the devices during manufacture, sterilization of the devices, or packaging of the devices for implantors.

2. The Patent in Suit

The present appeal involves AMS's '765 patent, which claims an apparatus and method for packaging a fluid-containing penile prosthesis in a pre-filled, sterile state. The prosthesis itself comprises a hydraulic, inflatable, fluid-permeable silicone cylinder with a fluid reservoir and pump contained in the cylinder, which is self-contained such that the entire prosthesis is implanted into the penis. Both the Hydroflex and the Flexi-Flate are this type of device. The packaging comprises a sterile, fluid-filled inner package that holds the pre-filled prosthesis and a non-sterile outer package that contains the inner package in a sterile state. This packaging configuration is referred to in the industry as the "wet pack."

AMS filed its application claiming the combination of a pre-filled prosthesis stored in the double layer packaging on December 27, 1984. The '765 patent issued from this application on July 1, 1986. Claims 1-12 and 21-24

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[7] (...continued)
unrelated to the '779 interference, other than by MEC's contentions that it was required to be disclosed pursuant to the warranty provisions of the Hakky agreement.

of the '765 patent are directed to the apparatus comprising the pre-filled and pre-sterilized packaged prosthesis. Claims 14-15 and 18-20 of the '765 patent are directed to the method of making and sterilizing a packaged pre-filled and pre-sterilized prosthesis.

The prior art unfilled prosthesis, such as the dry-pack Hydroflex or dry-pack Flexi-Flate, required filling in the operating room prior to implantation. This was undesirable because it increased the operating time required to implant the prosthesis and could lead to certain problems due to improper filling or leaking.

The subject matter of the '765 patent solved the problems of the prior art dry-pack configuration devices by pre-filling the prosthesis with a saline solution and immersing it in a foil pouch filled with a saline solution having the same osmotic properties as the solution within the prosthesis. This allowed the liquid level within the device to be maintained at a precise level while in storage prior to implantation. This inner foil pouch was then sterilized and stored inside an outer non-sterile container. The two layer packaging configuration allowed for a non-sterile nurse to open the non-sterile outer package and present the sterile inner package containing the pre-filled prosthesis to a sterile nurse to open in the operating field. Because of these asserted advantages, there was a much greater demand in the market for a pre-filled, pre-sterilized prosthesis over an unfilled device.

3. MEC's Infringement

MEC began to work on the problem of marketing a pre-filled, sterilized packaged version of its Flexi-Flate

prosthesis in early 1984. MEC's original packaging concept involved placing the pre-filled prosthesis in a rigid vapor impermeable tube containing saline of the same osmolarity as that within the device. The rigid tube was then enclosed in a slightly larger tube or pouch. MEC also attempted reversing the relationship of the tube and the pouch. None of these attempts to design a pre-filled packaged prosthesis proved to be successful, however, due to problems with leaking and sterilization.

In May of 1985, MEC personnel saw AMS's pre-filled, sterilized Hydroflex prosthesis in the wet pack packaging configuration at the annual American Urological Association trade show. The AMS package at the trade-show was not marked with any patent pending notice, and no representations were made at that time that any patent applications had been filed. MEC abandoned its previous packaging configurations after it obtained a sample of the Hydroflex device and packaging, which it referred to in creating its own double foil pouch wet pack packaging. MEC then introduced its own wet pack "Flexi-Flate" prosthesis in the market in May 1985. MEC also filed a patent application on its pre-filled product and package, but the application was later abandoned.

MEC became aware of the '765 patent shortly after it issued in late July 1986, through the efforts of its in-house patent counsel, Stuart Krieger.[8] AMS's patent counsel, James Elacqua, also called Krieger twice in August 1986, to advise MEC of the existence of the '765

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[8] Krieger was actually employed by Bristol-Myers, of which MEC is a subsidiary. Krieger was responsible for MEC's patent matters and acted as an in-house counsel for MEC.

patent. No accusation of infringement was made by AMS at that time, however. Krieger immediately contacted MEC's vice president for scientific affairs, Garry Carter, to advise him of the patent. Krieger also testified that he authorized performance of several patent validity searches on the '765 patent. These opinions were withheld at trial, however. At the end of August or the beginning of September of 1986, Krieger informed MEC's president, Robert Helbling, in an oral opinion that the '765 patent was invalid for obviousness and that MEC's wet pack Flexi-Flate fell literally within the scope of the '765 patent claims.

Shortly after learning of AMS's '765 patent, MEC began work on an alternative packaging configuration for its pre-filled device, known as the "vacuum pack." MEC did not begin selling the vacuum pack in the market until about January 1988. Even after development of the vacuum pack, MEC continued to ship its remaining inventory of the wet pack Flexi-Flate throughout the remainder of 1988.

4. The '765 Patent Litigation

AMS filed a complaint on October 28, 1987, accusing MEC of willful infringement of claims 1-12, 14-15, 18-20 and 21-24 of the '765 patent. The original complaint contained a jury demand and the case was docketed as a jury case. Although counsel for AMS informed counsel for MEC that the complaint had been filed, the complaint was not served at the time of filing. Settlement discussions ensued between the parties.

Meanwhile, in early November 1987, MEC contacted Mrs. Jamie Smith of Allegretti & Witcoff to conduct a validity evaluation of the patent. Smith provided an oral opinion to Krieger in December 1987 or January 1988, concluding that the '765 patent was invalid for obviousness, and that some claims were arguably anticipated. Smith put her opinion in writing, at Krieger's request, on February 24, 1988.

The settlement discussions between the parties were unsuccessful. In February 1988, AMS filed and served an amended complaint which differed from the original complaint only in that it did not contain a jury demand. MEC filed its Answer to the Amended Complaint on June 1, 1988, and later filed an Amended Answer and Counterclaims to the Amended Complaint on February 1, 1989. MEC's counterclaims included a request for declaratory judgment of invalidity and noninfringement as well as a breach of warranty claim and three counterclaims charging AMS with intentional, negligent, and fraudulent misrepresentation. The pleading did not mention a jury trial, however.

MEC's counterclaims for breach of warranty and for tortious misrepresentation were based primarily on the Hakky settlement agreement. MEC alleged that under the terms of the warranty provisions of the Hakky agreement, AMS "warranted that there [were] no other . . . pending applications for letters patent . . . with respect to any device disclosed to [MEC] . . . which would result in any infringement or other potential litigation." [¶ 17.8 Hakky agrmt.] The Klatt application, which matured into the '765 patent, was pending during the final negotiations of the Hakky agreement. Therefore, MEC argues

that AMS's failure to disclose the pending Klatt application was a breach of warranty because AMS knew that it was likely to result in litigation between the parties. MEC further alleged, in three additional counterclaims, that the "breach of warranty" resulting from AMS's nondisclosure amounted to a tortious misrepresentation.

In May of 1991, MEC moved for a jury trial relying on the jury trial demand in the original complaint. The district court denied MEC's motion on the basis that the original complaint was never served as required by Rule 38, Fed. R. Civ. P, and that therefore there had never been a proper demand for a jury trial. The court also noted that the issue of a jury trial was never raised in the pretrial conference in July of 1990. The district court concluded that the right to a jury trial had been waived.

5. The District Court Decision

MEC stipulated that its Flexi-Flate prosthesis would infringe the '765 patent, if valid, but argued at trial that the '765 patent was invalid for obviousness. The district court held that the '765 patent was not invalid for obviousness and therefore, in accord with MEC's stipulation, found infringement by MEC's wet pack Flexi-Flate. The district court further found that MEC willfully infringed the '765 patent and awarded enhanced damages of 1.5 times AMS's proven lost profits and reasonable royalties.

On MEC's warranty counterclaim, the district court found that the Hakky agreement was unambiguous and required the parties to disclose only those patents and applications implicated by the limited current technical

disclosures relating to the interference. Therefore, AMS was not required to disclose the '765 patent application because it did not relate to the interference. Consequently, the district court concluded that AMS did not breach any warranty in failing to disclose the '765 patent application to MEC as part of the interference settlement agreement. Likewise, with respect to MEC's misrepresentation counterclaims, the district court found that AMS made no misrepresentation of fact in not disclosing the application leading to the '765 patent to MEC because it "was not within the scope of the interference and consequently was not required to be revealed in order to comply with the warranty." *American Medical Sys., Inc. v. Medical Eng'g Corp.*, 794 F. Supp. 1370, 1404, 26 USPQ2d (BNA) 1081, 1105 (E.D. Wis. 1992).

As damages, AMS asserted entitlement to lost profits for the period of July 1, 1986 (the issue date of the '765 patent), through December 1987, after which MEC's non-infringing "vacuum pack" Flexi-Flate entered the market. From January 1988 on, AMS claimed entitlement to a reasonable royalty for MEC's continued shipping of its remaining inventory of the wet pack Flexi-Flates.

In awarding damages, the district court noted that AMS did not begin to mark its Hydroflex device until two months after the patent issued and that AMS did not begin shipping those marked devices until October 15, 1986. From this, the district court concluded that more than a *de minimis* number of devices was shipped without any patent marking pursuant to 35 U.S.C. § 287(a). Accordingly, the district court held that AMS was only entitled to damages from the date that it gave MEC actual notice of infringement. The district court further

found that actual notice was not given until the present lawsuit was filed on October 28, 1987. Therefore, the district court found that AMS was entitled to lost profits for the period of October 28, 1987 through December 1988, in the amount of $906,806.00, and to a reasonable royalty for the period of January 1988 to December 1988 in the amount of $46,264.24. This equals a total amount of $953.070.24 in lost profits and reasonable royalties, multiplied by 1.5, resulting in total damages of $1,429,605.30.

MEC appeals the district court's award of enhanced damages and challenges the finding of willfulness. Additionally, MEC argues that the district court erroneously construed the warranty provision of the Hakky agreement. Finally, MEC argues that the district court wrongfully denied its request for a jury trial under the Seventh Amendment.

AMS cross-appeals the district court's limitation of recoverable damages because of its initial failure to mark its patented product pursuant to 35 U.S.C. § 287(a).

ANALYSIS

I.

A. Willfulness

MEC argues that the district court applied the wrong legal standard in determining willfulness and, therefore, this finding should be overturned. A finding of willfulness requires the factfinder to find that clear and convincing evidence shows "that the infringer acted in disregard of the patent . . . [and] had no reasonable basis

for believing it had a right to do the acts." *Stickle v. Heublein, Inc.*, 716 F.2d 1550, 1565, 219 USPQ (BNA) 377, 378 (Fed. Cir. 1983). This is a factual determination to be made after consideration of the totality of the circumstances. *Studiengesellschaft Kohle, m.b.H. v. Dart Indus., Inc.*, 862 F.2d 1564, 1573, 9 USPQ2d (BNA) 1273, 1282 (Fed. Cir. 1988). In making a determination of willfulness, the court is also required to consider mitigating or ameliorating factors. *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826, 23 USPQ2d (BNA) 1426, 1435 (Fed. Cir. 1992). We review the court's determination of willfulness under a clearly erroneous standard. *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1580, 24 USPQ2d (BNA) 1321, 1338 (Fed. Cir. 1992).

MEC contests the willfulness finding by relying on the district court's statement that "[b]asically, there was a lack of evidence of good faith rather than explicit evidence of bad faith." 794 F. Supp. at 1399, 26 USPQ2d (BNA) at 1101. Based on this language, MEC argues that the district court applied the wrong legal standard, erroneously requiring MEC to prove "good faith" to avoid a finding of willfulness and a possible award of enhanced damages.

We reject MEC's contention that the district court applied the wrong legal standard. The language cited and relied on by MEC that indicates that the district court considered MEC's "lack of good faith" appears in a section of the opinion discussing the district court's denial of attorney fees. Therefore, it is not conclusive of the willfulness standard applied by the district court. In any event, in the section of the opinion dealing specifical-

ly with willfulness, the district court clearly set out the correct legal standard. *Id.* at 1395, 26 USPQ2d (BNA) at 1098. The context of the district court's specific discussion of willfulness clearly indicates that it applied the correct legal standard. Therefore, it is clear that MEC's argument is based solely on one passing statement taken out of context, and provides no grounds for reversal. *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 895 F.2d 1403, 1406, 13 USPQ2d (BNA) 1871, 1874 (Fed. Cir. 1990) ("[J]udgments, not words, are appealable."); *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 718, 223 USPQ (BNA) 1264, 1272 (Fed. Cir. 1984) (this court reviews "final decisions, not passing comments").

Moreover, the district court considered the totality of the circumstances in reaching its determination that MEC willfully infringed the '765 patent. The district court found that MEC knew of the '765 patent shortly after it issued in July of 1986, through the efforts of its in-house patent counsel, Krieger. Krieger informed MEC that its Flexi-Flate product infringed the '765 patent. The district court also found that MEC had no reasonable good faith belief to justify its continued infringement because Krieger's oral invalidity opinion lacked credibility and because the Smith opinion, though credible, came too late to be reasonably relied upon because "it was not rendered until MEC had been infringing the ['765] patent for almost twenty months." 794 F. Supp. at 1398, 26 USPQ2d (BNA) at 1101. Moreover, the district court found that "[t]he [Smith] opinion was written after MEC had stopped making the wet pack, and after suit had been filed," and further, that "Mr. Helbling [MEC's presi-

dent] had no knowledge of the Smith opinion in 1986-87 and testified that he relied only on Mr. Krieger's [oral] opinion." *Id.*, 794 F. Supp. at 1398, 226 USPQ2d at 1101. MEC does not challenge these findings, which we thus have no basis to overturn as clearly erroneous. Furthermore, MEC chose to withhold all of the documentary evidence of prior searches and outside counsel opinions upon which Krieger allegedly relied in rendering his oral opinion, from which the district court properly drew a negative inference. *Fromson v. Western Litho Plate & Supply Co.*, 853 F.2d 1568, 1572-73, 7 USPQ2d (BNA) 1606, 1611 (Fed. Cir. 1988) ("Where the infringer fails to introduce an exculpatory opinion of counsel at trial, a court must be free to infer that either no opinion was obtained or, if an opinion were obtained, it was contrary to the infringer's desire to initiate or continue its use of the patentee's invention."). Finally, the court found that MEC deliberately copied the AMS package design in developing its infringing dual pouch Flexi-Flate wet pack product. MEC has not shown these fact findings to be clearly erroneous.

Despite these findings, MEC argues that the district court erred in reaching its ultimate determination of willfulness because it allegedly ignored certain mitigating or ameliorating factors. According to MEC, these mitigating factors include the fact that it began designing a non-infringing alternative to the wet pack Flexi-Flate, the vacuum pack, soon after learning of the patent along with AMS's delay for an extended period of time before giving any notice of infringement to MEC. Therefore, MEC asserts that, considering these factors, the district court's determination of willfulness is clearly erroneous.

This argument also fails. The fact that these factors were not specifically mentioned in the district court's discussion of willfulness does not support the conclusion that they were not considered. All of the factors raised by MEC were discussed by the district court at some point in its opinion. Furthermore, none of the factors mentioned by MEC are inconsistent with a finding of willfulness. MEC's attempt to design a non-infringing alternative does not negate MEC's continuing sales of infringing devices during the redesign period. Nor does AMS's delay in filing suit negate the fact that MEC had actual knowledge of the '765 patent and had no reasonable basis upon which to rely in its continued infringement. Moreover, it is apparent that the district court took into account mitigating factors in determining the degree of willfulness, because it chose to award enhanced damages of only 1.5 times the total amount rather than awarding the maximum treble damages allowable under 35 U.S.C. § 284 (1988). An award of enhanced damages under section 284 is within the discretion of the district court and will not be overturned absent a clear showing of abuse of discretion. *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1547-48, 221 USPQ (BNA) 1, 8 (Fed. Cir. 1984).

Because MEC has failed to show any legal or factual error by the district court, we uphold the court's finding of willfulness. Additionally, we affirm the district court's award of enhanced damages because MEC has failed to show that the district court abused its discretion in this matter.

B. Breach of Warranty

On appeal, MEC also argues that the district court erred as a matter of law in construing the warranty agreement between AMS and MEC. The district court found that the warranty provision contained in paragraphs 17.7 and 17.8 of the Hakky agreement was unambiguous. The district court further found that the unambiguous language of the " 'warranty' in 17.8 requires the parties to disclose only those patents implicated by the limited 'current technical disclosures' referred to paragraph 17.7." 794 F. Supp. at 1401, 26 USPQ2d (BNA) at 1103. The district court then concluded that because the '765 patent did not relate to the '779 interference, its disclosure was not required and, therefore, AMS did not breach the warranty for failing to disclose the pending application. *Id.*, 26 USPQ2d (BNA) at 1103.

Contrary to its position at trial, MEC argues on appeal that the district court correctly held that the warranty provision of the Hakky agreement is unambiguous.[9] MEC also agrees with the district court that para-

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[9] AMS argues that MEC waived its argument on appeal that the warranty provision was unambiguous, because at trial MEC took the contrary position that the warranty provision was ambiguous. *Braun, Inc. v. Dynamics Corp. of Am.*, 975 F.2d 815, 821, 24 USPQ2d (BNA) 1121, 1126 (Fed. Cir. 1992) (argument that failure to introduce empirical evidence precluded finding of design patent infringement waived where issue of sufficiency of evidence was not raised before district court); *Libertyville Datsun Sales, Inc. v. Nissan Motor Corp. in U.S.A.*, 776 F.2d 735, 737 (7th Cir. 1985) (argument based on amendment to agreement waived because not made at trial

(continued...)

graphs 17.7 and 17.8 are interrelated. However, MEC argues that the unambiguous language of the agreement is broader than the district court's interpretation. MEC argues that the district court's interpretation reads additional limitations into paragraph 17.8 by concluding that any required disclosure under the warranty must have some relation to the '779 interference. According to MEC, the plain language of paragraph 17.8 required AMS to disclose any patent or application which may result in any potential litigation with respect to the disclosed Flexi-Flate device. Therefore, MEC asserts that the Klatt application should have been disclosed under the warranty, because AMS should have reasonably known that it would result in potential litigation between the parties.

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[9] (...continued)
even where general issue of interpretation of agreement and amendment was before district court).

The cases cited by AMS are distinguishable, however, because in those cases a party attempted to present arguments that were not actually considered by the district court. In this case, however, the precise issue of whether the warranty provision was ambiguous or unambiguous was put before the district court. Furthermore, the district court did actually determine that the agreement was unambiguous and interpreted the specific language of the agreement that is relied upon by MEC in its arguments on appeal as such as a matter of law. Therefore, even though MEC argued at trial that the warranty provision was ambiguous, it is not prevented from arguing on appeal that the district court's interpretation of the unambiguous language was incorrect as a matter of law because its arguments on appeal raise nothing that was not considered by the district court.

State law, in this case Wisconsin law, controls in matters of contract law and interpretation. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1241, 9 USPQ2d (BNA) 1913, 1924 (Fed. Cir.), *cert. denied*, 493 U.S. 853, 107 L. Ed. 2d 112, 110 S. Ct. 154 (1989); *Universal Gym Equip., Inc. v. ERWA Exercise Equip. Ltd.*, 827 F.2d 1542, 1550, 4 USPQ2d (BNA) 1035, 1040 (Fed. Cir. 1987). Interpretation of an unambiguous contract provision is a question of law which is subject to de novo review. *Lakeshore Commercial Fin. Corp. v. Drobac*, 107 Wis. 2d 445, 457, 319 N.W.2d 839, 843 (1982).

The warranty provision of paragraph 17.8 provides that each party warrants that there are no "pending applications . . . with respect to any device disclosed to the warranting party by the other party which would result in any infringement or other potential litigation issue." Looking at the plain language of these provisions, we conclude, as did the district court, that the "disclosure" referred to in paragraph 17.8 relates back to the "current technical disclosure . . . with respect to the patent issues in the '779 interference" specified by paragraph 17.7. Therefore, as a matter of law, the warranty only applies to those pending applications implicated by the devices that were disclosed relating to the patent issues of the '779 interference.

To interpret the warranty provision as MEC urges, i.e., that any application which could result in any potential litigation whatsoever with any disclosed device, reads the warranty provision out of context. The "disclosures" referred to in paragraphs 17.7 and 17.8 were made specifically with respect to the patent issues involved in the '779 interference. The district court found

that the subject matter of the '765 patent did not relate to "the patent issues in the '779 interference." 794 F. Supp. at 1401, 26 USPQ2d (BNA) at 1103. MEC does not contest this finding. Therefore, the '765 patent application was not required to be disclosed under paragraph 17.7. Moreover, the facts are undisputed that neither party disclosed anything relating to the pre-filling, pre-sterilizing or packaging of their respective devices which would have implicated the Klatt application, thereby requiring disclosure pursuant to paragraph 17.8. Hence, we conclude that the district court correctly determined that disclosure of the Klatt application was not required by the terms of the Hakky agreement and, consequently, that there was no breach of warranty.

C. Jury Trial

MEC argues that the district court erroneously deprived it of its Seventh Amendment right to a jury trial. The district court denied MEC's pretrial motion for a jury trial, ruling that the original complaint containing the jury demand had never been served as required by Rule 38(b), Fed. R. Civ. P.[10] MEC asserts, however, that

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[10] Rule 38(b) provides in relevant part:

> (b) Demand. Any party may demand a trial by jury . . . by serving upon the other parties a demand therefor in writing at any time after the commencement of the action and not later than 10 days after the service of the last pleading directed to such issue. Such demand may be indorsed upon a pleading of the party.

Also relevant is Rule 38(d) which provides in relevant part:

(continued...)

the district court made a contrary "finding" in its opinion that the original complaint had been served. In its discussion of "hard ball litigation tactics" in the "attorney fees" section of its opinion, the district court stated that "AMS filed the original complaint in this matter in October 1987, but did not *serve* it, until December 1987." 794 F. Supp. at 1399, 26 USPQ2d (BNA) at 1102. Based on this one statement, MEC argues that the original complaint was served and that it never consented to withdrawal of the jury demand as required by Rule 39(a), Fed. R. Civ. P.[11] Therefore, MEC asks this court to vacate the district court's judgment and remand for a jury trial.

Once again, MEC is relying on a stray comment in the district court's opinion to try to create a basis for its argument. There is no indication in the record that the

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[10] (...continued)

(d) Waiver. The failure of a party to serve a demand as required by this rule . . . constitutes a waiver by the party of trial by jury. A demand for trial by jury made as herein provided may not be withdrawn without the consent of the parties.

[11] Rule 39(a), Fed. R. Civ. P., provides in relevant part:

When trial by jury has been demanded as provided in Rule 38, . . . the trial of all issues so demanded shall be by jury, unless (1) the parties or their attorneys of record, by written stipulation filed with the court or by an oral stipulation made in open court and entered in the record, consent to trial by the court sitting without a jury or (2) the court upon motion or of its own initiative finds that a right of trial by jury of some or all of those issues does not exist under the Constitution or statutes of the United States.

jury trial issue was before the court at trial,[12] let alone that the court's statement was intended to be a "finding" contradictory to its earlier ruling on MEC's motion that the original complaint was not served. Judge Stadtmueller's earlier finding that no jury demand had been served is supported by the record evidence. In making his ruling, the judge noted that in the Rule 16 pretrial conference occurring over a year before MEC's jury trial motion, neither party indicated that it was seeking a jury trial. Additionally, the court noted that in an earlier deposition, MEC's counsel, Mr. Banner, acknowledged that he was "not suggesting anything with regard to the matter of a jury trial." The court further noted that there was nothing in the record to establish that the original complaint had been served. The district court therefore concluded that "the matter of a jury trial was long ago waived." We repeat our earlier caution that this court reviews decisions, not statements in opinions. *Lindemann*, 895 F.2d at 1406, 13 USPQ2d (BNA) at 1874. We conclude that this passing statement does not constitute a contrary "finding" by the district court.

In addition, we note that the authority relied on by MEC to establish entitlement to a jury trial, *Thomson v. Jones*, 102 F.R.D. 619 (N.D. Ill. 1984), is inapposite. In *Thomson*, not only was the original complaint with the jury demand actually served on defendants, but the defendants' answer to the complaint demanded a jury trial. Here, by complete contrast, neither was the original com-

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[12] The record shows that MEC failed to include the jury demand issue in the Rule 16 pretrial order or to otherwise raise the issue at trial.

plaint with the jury demand served nor was a jury demanded in the answer or amended answer, the latter of which was filed almost two years before the motion for a jury trial.

We conclude that MEC's argument is without merit.

II.

A. Patent Marking

AMS cross-appeals the district court's limitation of its recoverable damages to the period after the filing date of this lawsuit for failure to mark under 35 U.S.C. § 287(a),[13] claiming that the district court erroneously construed the statute. Statutory construction is a legal question which we review *de novo*. *Hoechst Aktiengesellschaft v. Quigg*, 917 F.2d 522, 526, 16 USPQ2d (BNA) 1549, 1552 (Fed. Cir. 1990).

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[13] 35 U.S.C. § 287(a) provides:

> Patentees, and persons making or selling any patented article for or under them, may give notice to the public that the same is patented, either by fixing thereon the word "patent" or the abbreviation "pat.", together with the number of the patent, or when from the character of the article, this can not be done, by fixing to it, or to the package wherein one or more of them is contained, a label containing a like notice. In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for the infringement occurring after such notice.

The district court found, and the parties do not dispute the following facts. The '765 patent issued on July 1, 1986. Prior to issuance of the '765 patent, AMS had already shipped 8,556 unmarked prostheses. 794 F. Supp. at 1392, 26 USPQ2d (BNA) at 1095 . AMS did not begin marking its product until about two months after issuance of the '765 patent, and did not begin shipping its marked products until October 15, 1986, three and one-half months after the patent issued. *Id.*, 26 USPQ2d (BNA) at 1095. During the period after issuance of the patent, 1,939 prostheses were shipped without marking. *Id.*, 26 USPQ2d (BNA) at 1095. Relying on *Hazeltine Corp. v. Radio Corp. of Am.*, 20 F. Supp. 668, 35 USPQ 438 (S.D.N.Y. 1937), the district court concluded that, under section 287(a), AMS was "obliged to have marked all Hydroflexes subsequent to issue [sic] of the patent, except that it is allowed a relatively small number to be shipped unmarked as it readies the marking process." 794 F. Supp. at 1391, 26 USPQ2d (BNA) at 1095 (citing 5 Donald S. Chisum, *Patents*, §§ 20.03[7][c][iii] n.109 and [c][iv] & n.133). The district court found that AMS failed to comply with section 287(a) because it had shipped more than a de minimis number of products after the patent issued without the requisite marking. *Id.* at 1392, 26 USPQ2d (BNA) at 1095.

AMS argues that the district court erroneously interpreted section 287(a). Under the correct interpretation of section 287(a), AMS asserts that it is entitled to damages from the time that it began consistently marking its product, thereby satisfying the statutory requirement. According to AMS, the district court's reliance on *Hazeltine* is misplaced, because that case was decided under

Revised Statute 4900, ch. 67, 44 Stat. 1058-59 (1927), the predecessor statute to the current section 287(a). R.S. 4900 provided that "it shall be the *duty* of all patentees . . . to give sufficient notice to the public that the same is patented . . ." (emphasis added). In 1952, Congress amended R.S. 4900 to become the present section 287(a), changing the language to make marking permissive rather than mandatory, so that a "patentee . . . *may* give notice to the public" by the specified marking. Act of July 19, 1952, ch. 950, § 287, 66 Stat. 813. Although the legislative history does not shed much light on Congress's intent regarding this specific language change, it is clear that the amendments were meant to reorganize and clarify the prior provisions.[14] AMS argues that since *Hazeltine* and the 1952 amendments, the courts have interpreted the new marking provision to allow damages from the point at which the statute is complied with by

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[14] The legislative history of section 287(a) is rather sparse, but the purpose of the amendments was generally described in the Senate Report as follows:

> The next few sections relate to . . . [*inter alia*] marking and notice; all of which together replace present statutes on suits, with a good deal of reorganization in language to clarify the statement of the statutes.
>
> * * * *
>
> Section 287 - Section Revised
>
> Based on title 35, U.S.C., 1946 ed., § 49 (R.S. 4900, amended Feb. 7, 1927, ch. 67, 44 Stat. 1058).
>
> Language is changed. The proviso in the corresponding section of existing statute is omitted as being temporary in character and now obsolete.

S. Rep. No. 1979, 82d Cong., 2d Sess. 9, 30 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2403, 2423.

fully marking the patented device. AMS also argues that Hazeltine is not applicable to the present situation, because in that case, marking was haphazard and, therefore, the statute was never fully complied with at any time.

Specifically, AMS points to *Slimfold Manufacturing Co. v. Kinkead Industries, Inc.*, C.A. No. 1:78-CV-1978-JOF, 1990 WL 512961 (N.D. Ga. May 29, 1990), *aff'd*, 932 F.2d 1453, 18 USPQ2d (BNA) 1842 (Fed. Cir. 1991). In *Slimfold*, the patentee commercialized the invention before the patent issued on May 14, 1974, but did not begin marking the patented product until November 1, 1977. *Id.*, slip op. at 16. The defendant began infringing in June 1977, the first actual notice of infringement was given in March 1978, and suit was filed in October 1978. *Id.* at 10, 16, 1. The district court held that Slimfold was entitled to damages from November 1, 1977, when it began to consistently mark its patented products. In reaching this conclusion, the court reasoned that:

> The statute does not require marking within a particular time after issuance of a patent. Both the Fifth and Sixth Circuit Courts of Appeal have so held. *Wm. Bros. Boiler & Mfg. Co. v. Gibson-Stewart Co.*, 312 F.2d 385, 386, 136 USPQ (BNA) 239, 240 (6th Cir. 1963); and *Bros, Inc. v. W.E. Grace Mfg. Co.*, 320 F.2d 594, 599, 138 USPQ (BNA) 357, 359 (5th Cir. 1963): "The Court points out that there is '. . . nothing in the statute requiring marking or notice within any period after issue as a condition for recovery of damages for infringement. . . .' " Liability for infringement begins with marking (or actual notice) whenever that occurs.

Id. at 32-33. On appeal, the Federal Circuit specifically affirmed the district court's award of damages as of the marking date, although the specific question of the proper interpretation of section 287(a) was not before the court. 932 F.2d at 1456, 1459, 18 USPQ2d (BNA) at 1845, 1847.

As noted by the district court in *Slimfold*, both the Fifth and Sixth Circuits have in the past specifically interpreted section 287(a) to allow damages from the time that actual marking begins or from the time of actual notice of infringement, whichever comes first. In *Wm. Bros Boiler & Manufacturing Co. v. Gibson-Stewart Co.*, 312 F.2d 385, 136 USPQ (BNA) 239 (6th Cir. 1963), the Sixth Circuit held that although the patentee failed to mark its patented devices for nine months after the date that the patent issued, he was entitled to recovery of damages from the time of compliance with the marking provisions of the statute. *Id.*, 136 USPQ (BNA) 239. The holding was based on the district court's reasoning that

> "Unless and until the patentee marks his patent or serves actual notice upon an alleged infringer he can recover no damages, but . . . nothing in the statute requires marking or notice within any period after issue as a condition for recovery of damages for infringement. . . . The penalty for failure to do either [is] limited to denial of damages for infringement at any time prior to compliance with the requirements of the statute."

Id. at 386, 136 USPQ (BNA) at 240. In a related case, *Bros, Inc. v. W.E. Grace Manufacturing Co.*, 320 F.2d 594, 138 USPQ (BNA) 357 (5th Cir. 1963), the Fifth

Circuit followed the same reasoning in reversing the district court's limitation of damages to the filing date of the lawsuit, allowing recovery of damages from the date of marking.

Similarly, in *Briggs v. M&J Diesel Locomotive Filter Corp.*, 228 F. Supp. 26, 63-64, 141 USPQ (BNA) 96, 127 (N.D. Ill. 1964), *aff'd*, 342 F.2d 573, 144 USPQ (BNA) 701 (7th Cir. 1965), the district court held that despite a two year delay in marking, the patentee was entitled to recover damages for infringement undertaken after marking began. Likewise, in *Mosinee Paper Corp. v. James River Corp.*, 1992 U.S. Dist. LEXIS 2425, 22 USPQ2d (BNA) 1657, 1662, 1992 WL 41690 (E.D. Wis. 1992), the district court determined that patentee was entitled to full recovery of damages where patentee began to mark the product in 1980, prior to infringement, even though the patent in suit issued on August 21, 1979.

MEC fails to adequately distinguish these cases or to convince us that their rationale is unsound. MEC cites a number of authorities in support of the district court's interpretation of the statute that marking of all patented products must begin immediately after issuance of the patent, subject to the *de minimis* exception of *Hazeltine*.[15]

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[15] MEC cites numerous cases standing for the proposition that *all* patented articles must be marked after issuance of the patent. *The Providence Rubber Co. v. Goodyear*, 76 U.S. (9 Wall.) 788, 801, 19 L. Ed. 566 (1869) (decided under the marking statute of 1861, Act of March 2, 1861, ch. LXXXVIII § 13, 12 Stat. 249 (1863)); *Crier v. Innes*, 170 F. 324, 326 (2d Cir. 1909) (decided under R.S. 4900, U.S. Comp. Stat. 1901, p. 3388); *Gordon v. Easy Washing Mach. Corp.*, 39 F. Supp. 202,

(continued...)

These cases were all decided under the predecessor statutes to section 287(a) and, therefore, are not controlling on the interpretation of the present statute. As discussed above, since the statute was amended in 1952, the cases which specifically address this issue have interpreted section 287(a) to allow damages from the time when marking begins in compliance with the statute or actual notice is given, whichever comes first.[16]

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[15] (...continued)
203, 49 USPQ (BNA) 321, 322 (N.D.N.Y. 1941) (decided under R.S. 4900, ch. 67, 44 Stat. 1058-59 (1927)); *Kilgore Mfg. Co. v. Triumph Explosives, Inc.*, 37 F. Supp. 766, 775, 49 USPQ 51, 53 (D. Md. 1941) (decided under R.S. 4900); *Matthews & Willard Mfg. v. National Brass & Iron Works*, 71 F. 518 (E.D. Pa. 1895) (decided under the marking statute of 1870, Act of July 8, 1870, ch. CCXXX § 38, 16 Stat. 203 (1871)). All of these statutes under which MEC's authorities were decided imposed a *duty* to mark on the patentee.

[16] Although other cases appear to be contradictory, they do not address the specific factual situation presented here. For example, *General Electric Co. v. Sciaky Bros., Inc.*, 304 F.2d 724, 726, 134 USPQ (BNA) 55, 57 (6th Cir. 1962), has been cited for the proposition that *all* patented products must be marked. All that *General Electric* says, however, is that "in view of General Electric's failure to mark its products as required by statute, or to give any notice of infringement, it could not, in any event, recover damages for infringements occurring prior to the filing of the action for infringement." (citations omitted). This case clearly does not address the situation where marking was fully complied with at some date after issuance. *See also Maxwell v. Baker*, 805 F. Supp. 728, 26 USPQ2d 1241 (D. Minn. 1992) (fact issue existed as to licensees failure to mark patented products); *In re Yarn Processing Patent Validity Litig.*, 602 F. Supp. 159, 168, 225 USPQ (BNA)
(continued...)

Although not binding on this court, we find the reasoning of the post-1952 cases highly persuasive. The plain language of section 287(a) does not provide any time limit by which marking must begin, nor does the legislative history indicate any such limitation.[17] Congress structured the statute so as to tie failure to mark with disability to collect damages, not failure to mark *at the time of issuance* with disability to collect damages. Furthermore, allowing recovery of damages from the point of full compliance with the marking statute furthers the policy of encouraging marking to provide notice to the public, even if initial marking after issuance of the patent is delayed. The sooner one complies with the marking requirements, the more likely one is to maximize the period of time for recoverable damages. To prevent recovery of damages for failure to immediately mark, however, provides no incentive for a patentee who inadvertently or unavoidably fails to mark initially to mark in the future.

Moreover, preventing recovery of damages for an initial failure to mark does not remedy the problem of having unmarked products in the marketplace. Any

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[16] (...continued)
765, 771 (W.D.N.C. 1984) (licensees of patent failed to mark products); *Miller v. Daybrook-Ottawa Corp.*, 291 F. Supp. 896, 158 USPQ (BNA) 635 (N.D.Ohio 1968) (inconsistent marking by patentee).

[17] The legislative history cited by MEC referring to the requirement to mark *all* or *each* patented article is not responsive to the question of whether Congress intended to deny damages even after the patentee begins to mark all patented articles.

products entering the market prior to issuance of the patent will not be marked. Even the *Hazeltine* court recognized that "it is not the number of articles seen by the defendant which is controlling on an issue of marking . . . but whether the patentee performed this statutory duty which was a prerequisite to his *in rem* notice to the world." *Hazeltine*, 20 F. Supp. at 671, 35 USPQ (BNA) at 442. Therefore, once marking has begun in compliance with the statute, *in rem* notice is provided and there is no reason to further limit damages on this account.

In light of the permissive wording of the present statute, and the policy of encouraging notice by marking, we construe section 287(a) to preclude recovery of damages only for infringement for any time prior to compliance with the marking or actual notice requirements of the statute. Therefore, a delay between issuance of the patent and compliance with the marking provisions of section 287(a) will not prevent recovery of damages after the date that marking has begun. We caution, however, that once marking has begun, it must be substantially consistent and continuous in order for the party to avail itself of the constructive notice provisions of the statute.

Applying this statutory construction to the facts of this case, AMS is entitled to damages from the time when it either began marking its products in compliance with section 287(a) or when it actually notified MEC of its infringement, whichever was earlier. AMS began marking its products about two months after issuance of the '765 patent and it began externally shipping those marked products on October 15, 1986. The district court found that actual notice of infringement was not given

until the lawsuit was filed on October 28, 1987. AMS has not shown that the district court's finding as to actual notice was clearly erroneous.[18]

We hold that AMS is entitled to damages from the time that it began shipping its marked products, October 15, 1986, rather than the filing date of the lawsuit as found by the district court, because AMS was in compliance with the marking statute at that time. The date that AMS began marking its products is irrelevant for purposes of the statute, because marking alone without distribution provides no notice to the public where unmarked products are continuing to be shipped. The purpose of the constructive notice provision is "to give patentees the proper incentive to mark their products and thus place the world on notice of the existence of the patent." *Laitram Corp. v. Hewlett-Packard Co.*, 806 F. Supp. 1294, 1296, 25 USPQ2d (BNA) 1827, 1834-35 (E.D. La. 1992). The world cannot be "put on notice" if the patentee marks certain products, but continues to ship unmarked products. Therefore, AMS was not in full compliance with the marking statute while it continued to ship its unmarked products, which continued to mislead

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[18] AMS argues that MEC was notified in August 1986 by its own counsel, Krieger, that MEC was infringing the '765 patent. This is clearly not what was intended by the marking statute. Section 287(a) requires a party asserting infringement to either provide constructive notice (through marking) or actual notice in order to avail itself of damages. The notice of infringement must therefore come from the patentee, not the infringer. *Devices for Medicine, Inc. v. Boehl*, 822 F.2d 1062, 1066, 3 USPQ2d (BNA) 1288, 1292 (Fed. Cir. 1987) ("Absent notice, [infringer's] 'knowledge of the patents' is irrelevant.").

the public into thinking that the product was freely available. Full compliance was not achieved until AMS consistently marked substantially all of its patented products, and it was no longer distributing unmarked products. We therefore remand this portion of the case to the district court for a proper determination of damages consistent with this decision.

B. Patent Marking Relating to Method Claims

AMS argues that the district court erred in limiting its recoverable damages from the infringed method claims of the '765 patent pursuant to section 287(a). The law is clear that the notice provisions of section 287 do not apply where the patent is directed to a process or method. *Bandag, Inc. v. Gerrard Tire Co., Inc.*, 704 F.2d 1578, 1581, 217 USPQ 977, 979 (Fed. Cir. 1983) (citing *Wine Ry. Appliance Co. v. Enterprise Ry. Equip. Co.*, 297 U.S. 387, 80 L. Ed. 736, 56 S. Ct. 528 (1936)); *Hanson v. Alpine Valley Ski Area, Inc.*, 718 F.2d 1075, 1083, 219 USPQ (BNA) 679, 685 (Fed. Cir. 1983) (noting that section 287(a) does not apply where only method claims are infringed). The district court, however, relied on *Devices for Medicine, Inc. v. Boehl*, 822 F.2d 1062, 3 USPQ2d (BNA) 1288 (Fed. Cir. 1987), in holding that "where there are both product and method claims being claimed infringed, the patentee must mark the product." 794 F. Supp. at 1391, 26 USPQ2d (BNA) at 1095.

In *Devices for Medicine*, the court noted that in *Bandag* and *Hanson*, a distinction was made between cases "in which only method claims are asserted to have been infringed" and cases where a patentee alleges in-

fringement of both the apparatus and method claims of the same patent. *Devices for Medicine*, 822 F.2d at 1066, 3 USPQ2d (BNA) at 1292. The *Devices for Medicine* court further stated that because the method claims of the patent were directed to the use of the claimed product, "having sold the product unmarked, [the patentee] could hardly maintain entitlement to damages for its use by a purchaser uninformed that such use would violate [patentee's] method patent." *Id.*, 3 USPQ2d (BNA) at 1292.

AMS contends that *Devices for Medicine* is inapposite, because in that case the patent contained product claims and claims covering the use of the same product. AMS asserts that the sale of a product carries an implied license to use it as a matter of law; therefore failing to mark a patented product rationally creates an expectation of receiving a right from the seller to use it for its customary purposes. By contrast, AMS argues that the '765 patent involves methods of making and sterilizing the patented product and that sale of a product does not grant any implied license to make an additional product or to use a particular manufacturing process to make it. Therefore, AMS asserts that the rationale of *Devices for Medicine* should not apply and that section 287(a) has no application to the instant method claims.

We find AMS's distinction of the claims in *Devices for Medicine* from those in the present action to be meaningless within the context of section 287(a). The purpose behind the marking statute is to encourage the patentee to give notice to the public of the patent. The reason that the marking statute does not apply to method claims is that, ordinarily, where the patent claims are directed to

only a method or process there is nothing to mark. Where the patent contains both apparatus and method claims, however, to the extent that there is a tangible item to mark by which notice of the asserted method claims can be given, a party is obliged to do so if it intends to avail itself of the constructive notice provisions of section 287(a).

In this case, both apparatus and method claims of the '765 patent were asserted and there was a physical device produced by the claimed method that was capable of being marked. Therefore, we conclude that AMS was required to mark its product pursuant to section 287(a) in order to recover damages under its method claims prior to actual or constructive notice being given to MEC.

C. Attorney Fees

We deny AMS's request for attorney fees based on its allegation that MEC's jury trial argument was so frivolous and unreasonable as to warrant sanctions. Although we found MEC's arguments on this issue to be meritless, this was but one issue in an appeal which otherwise was not frivolous. Moreover, meritlessness does not prove frivolity. "Even though an appeal is judged 'entirely without merit,' . . . it may have presented an arguable basis for reversal, and thus not qualify for sanctions." *Biodex Corp. v. Loredan Biomedical Inc.*, 946 F.2d 850, 863-64, 20 USPQ2d (BNA) 1252, 1263 (Fed. Cir. 1991) (citation omitted), *cert. denied*, 119 L. Ed. 2d 579, 112 S. Ct. 2957 (1992). Therefore we deny AMS's request for sanctions.

CONCLUSION

AFFIRMED-IN-PART, REVERSED-IN-PART and REMANDED.

87-C-1236 (JPS)

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

AMERICAN MEDICAL SYSTEMS, INC.,

Plaintiff,

v.

MEDICAL ENGINEERING CORPORATION,

Defendant.

June 25, 1992

OPINION

STADTMUELLER, District Judge.

I. Introduction

This action was filed by American Medical Systems, Inc. (AMS) against Medical Engineering Corporation (MEC) in October 1987. AMS owns, via assignment from William Klatt, U.S. Patent Number 4,597,765, entitled "Method and Apparatus for Packaging a Fluid Containing Prosthesis." AMS claims MEC has infringed the patent. MEC has counterclaimed for a declaration of invalidity of the patent, and for relief due to AMS' alleged breach of certain agreements between the parties. The case was tried to the court, sitting without a jury, for three weeks. Pursuant to Fed. R. Civ. P. 52 the following constitutes the court's findings of fact and conclusions of law.

II. The Parties and Jurisdiction

AMS is a Minnesota corporation with its principal place of business in Minnetonka, Minnesota. Its business is devoted to the research, development, manufacture and sale of penile prostheses and other medical products of a urological nature. AMS was an independent company until May 1985, when it became a wholly-owned subsidiary of Pfizer Inc.

MEC is a Delaware corporation with its principal place of business in Racine, Wisconsin. MEC's business, too, is devoted to medical products, including mammary and penile prostheses and urinary stents. Since 1982 MEC has been a wholly-owned subsidiary of the Bristol Myers-Squibb Corporation.

The jurisdiction of the court arises under 28 USC 1338(a). Venue is proper in this district pursuant to 28 USC 1400(b).

III. The Evolution of the Penile Prosthesis

Erectile dysfunction affects more than five million men in the United States. The causes range from the physiological to the psychological. Common physical causes include diabetes, neurological or vascular disease, prostrate surgery and spinal cord injuries, to name but a few. One of the recognized treatments for erectile dysfunction is the insertion of a penile protheses.

The first modern penile prosthesis, known as "rods" and "multi-component inflatables," were developed in the early 1970s and continue to be actively marketed. Both AMS and MEC manufacture the rod prosthesis: respec-

tively, the AMS 600 (Figure A)[1] and the MEC Flexi-Rod. The "rod" type device is generally comprised of cylinders of silicone material, sometimes with a metal wire core. Two cylinders are surgically implanted in the corpora cavernosa of the penis. The cylinders are always rigid, and at coitus are simply physically manipulated into position. The advantages of this device are that it is simple, inexpensive, easy to implant and essentially free from mechanical failure. On the other hand, the rods permanently rigidized the phallus, resulting in a lack of flaccidity and concomitant problems with concealment.

The multi-component inflatable device such as the AMS 700CX (Figure B) consists of a reservoir, at least one pump, and a pair of inflatable cylinders, all connected by tubing. Hence, the product is often referenced as a "three-piece" device. The reservoir is implanted in the patient's abdominal cavity, the pump in the scrotum, and the pair of cylinders in the corpora cavernosa. In operation, fluid is forced from the reservoir to the cylinders by pumping at the scrotum, which pressurizes and rigidizes the cylinders and phallus. Thereafter, a release valve in the pump can be activated to return the fluid to the reservoir, deflating the cylinders and returning the phallus to a flacid state. The advantages of this device are its superior rigidity, excellent flaccidity and concealment, and the natural look and feel it afforded. However, it requires more invasive surgery, is more expensive, and is more prone to malfunction.

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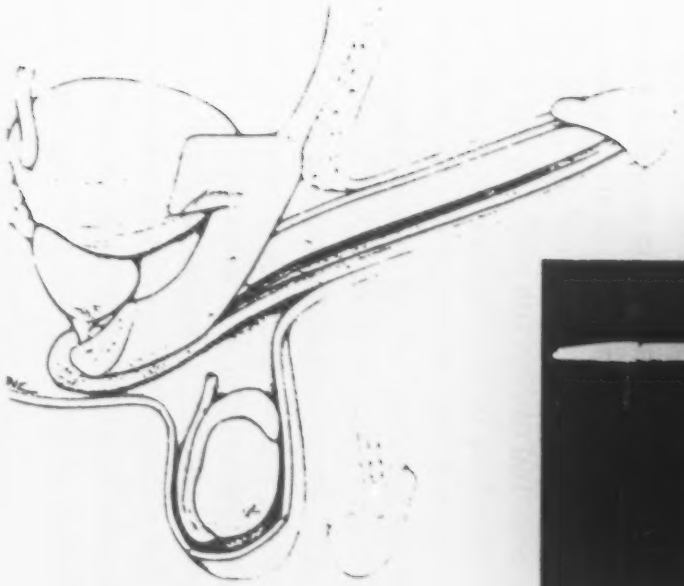
[1] Figures A, B and E appear in Exhibit 22.



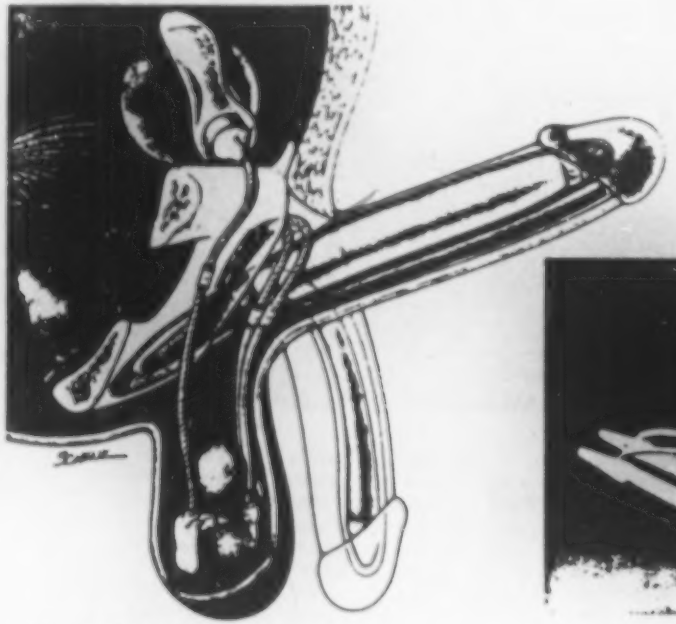
AMS Malleable 600™
Penile Prosthesis

The AMS Malleable 600™ Penile Prosthesis is permanently firm, but can be bent to an erect position for intercourse and close to the body for concealment.

Stainless-steel core

Malleable rod

Figure A



AMS 700CX™ Inflatable Penile Prosthesis

The AMS 700CX™ Inflatable Penile Prosthesis mimics the process of a normal erection. Squeezing the pump bulb in the scrotum a number of times makes the penis firm and erect. Compressing the release valve on the side of the pump returns the penis to a relaxed position.

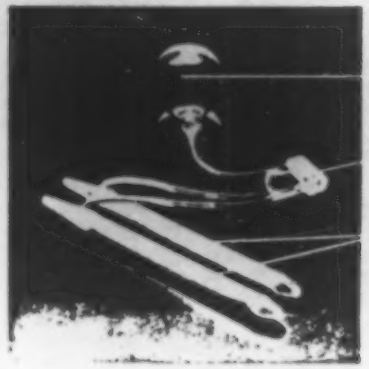


Figure B

Later in the 1970s both AMS and MEC independently began working on a "self-contained" prosthesis. Both designs consisted of a hydraulic, inflatable, fluid-permeable silicone cylinder with the reservoir and pump contained in the cylinder. Both efforts were geared to obtaining the benefits of the three-piece device while avoiding the multiple components and invasive surgery of the three-piece on the one hand and the permanent rigidity of the rods on the other.

MEC reached the market first, in October 1984, with a product called "Flexi-Flate." (Figure C).[2] The prosthesis was shipped sterile but unfilled—that is, without the saline necessary to drive the hydraulic components of the device. This "dry pack" configuration created problems.

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[2] Figure C appears in Exhibit 35 at page 3.

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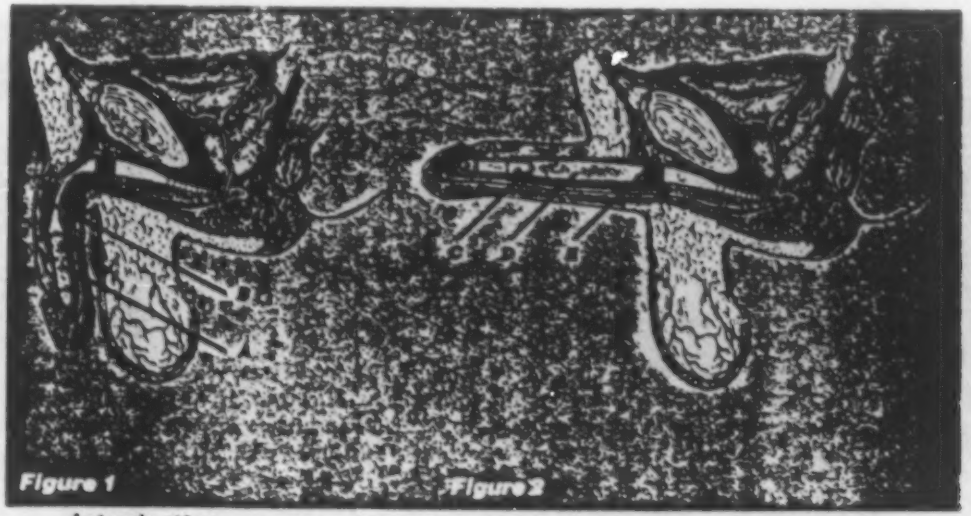

Figure 1 Figure 2

Introduction

The Flexi-Flate is a totally self-contained inflatable penile implant similar in appearance to rod-type prostheses such as the Flexi-Rod® II. Unlike multi-component inflatable devices the Flexi-Flate consists of two cylinders and is totally implanted within the corpora. This implant is a result of a long-term commitment by Medical Engineering Corporation to develop a simpler inflatable penile prosthesis.

The Flexi-Flate allows the patient with erectile impotence to create an erection by simply squeezing the pump ***(A-Figure 1)*** located proximally to the glans penis.

The erection is created when fluid is pumped from an expandable outer cylinder ***(B-Figure 1)*** through special one-way check valves ***(C-Figure 2)*** into a non-expandable inner cylinder ***(D-Figure 2)*** The penis becomes erect and rigid as fluid is transferred to the inner cylinder. To deflate the implant and return the penis to the flaccid state, the patient simply bends his penis at the base. This increases the pressure in the non-expandable inner cylinder. When the pressure in the inner cylinder exceeds the preset pressure relief valve setting, fluid is forced through the relief valve ***(E-Figure 2)*** and back into the outer cylinder.

Figure C

First, quality control was compromised, since MEC was unable to conduct final functional quality control testing on all the devices. The best that could be done was to test a sample and hope it was representative. There were also problems associated with filling the prosthesis in the operating room. The doctor had to open the patient to determine the appropriate size prosthesis. Then, while the patient was open, the doctor had to fill the two Flexi-Flate cylinders with saline and aspirate them in a procedure that could easily take up to 30 minutes for a surgeon new to the process. The saline had to be specially filtered during filling to avoid the small particulate matter normally found even in the sterile, hospital-grade variety; such particulate can clog the sensitive valves in the cylinders. (Ex. 36 at 7). In addition, the amount of saline to be added to a cylinder was less than a tablespoon, about 8-12 cc, depending on the size of the prosthesis. Precision was critical; underfilling would produce a prosthesis that did not properly rigidize, and overfilling would create a prosthesis which would not deflate properly. The record reflects a number of instances of improper filling during surgeries utilizing the dry-pack prosthesis. (Exs. 55, 58-61, 92-95).

IV. Klatt's Invention

In the 1970's AMS began developing its own self- contained penile prosthesis, called the Hydroflex. At least as early as January 1981 AMS knew that having a prefilled and sterile device would be important in the long run. (Ex. 533). By November 1983, AMS was actively seeking a method of providing a prefilled sterile device to the surgeon for surgical implant. (Tr. 1673-74; Ex. 511). The

responsibility for solving the problem was assigned to AMS engineer William Klatt.[3]

Klatt spoke with the designer of the Hydroflex device about its design characteristics. He also spoke to the marketing department to find out what kind of package characteristics they would want. He was told they wanted a small, easy to open, two layer package. This packaging would allow a non-sterile nurse to open the non-sterile outer package and present the sterile inner package to a sterile nurse to open in the operating field. Mr. Klatt also spoke with a number of packaging material suppliers, including Kapak Corporation, whose pouches were ultimately used to package the Hydroflex. (Tr. 1675, 1687-1690). In addition, he discussed sterilization methods and sterilization validation with an AMS quality control engineer, John Westrom, and an independent consultant, Skyland Laboratories. (Tr. 1674-76). Mr. Klatt had generally conceived his solution by December 1983: "Place [prefilled Hydroflex] in package, fill package with .9% salt solution, seal package, sterilize." (Tr. 1678; Ex. 511 at Bates 217). Testing and validation of the solution, however, continued until at least late 1984. (Tr. 1684; Ex. 511).

The wet pack configuration had clear advantages over the dry pack. The prosthesis could be accurately filled

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[3] Mr. Klatt has a bachelor of science degree in electrical engineering. It appears Mr. Klatt was somewhat of a jack-of-all-trades engineer at AMS. His previous work for AMS included design of electronic circuitry used in diagnostic equipment; mechanical and pneumatic design of an unspecified nature; and the design of wood and metal cabinets. (Tr. 1665-67).

with particulate-free saline, and the device could be sterilized by the manufacturer before shipment. This guaranteed quality control to the fullest extent possible by eliminating the intervening operating room filling procedure before implantation. As a result, the functional properties of the device would not change from the time of manufacture to the time of implantation. In addition, since there was no filling to be done in the operating room, the surgeon was able to immediately implant the device. The elimination of the intervening step reduced the amount of time the patient was under anesthesia, as well as the overall cost of the surgical procedure.[4]

AMS sought to patent the combination of prefilled Hydroflex and packaging created by Mr. Klatt. The invention is fully described in the patent, and discloses how to make and use the invention to obtain its benefits. The patent claims are divided into product claims and method claims. The former, claims 1-12 and 21-24, define the prefilled and presterilized packaged prosthesis. Claim 2 is representative of the product claims:[5]

> A packaged fluid containing prosthesis adapted to be implanted in a sterile condition, said prosthesis comprising:
>
> > a prosthetic device, wherein said prosthetic device is an inflatable penile prosthesis, having a closed, permeable housing defining a fluid containing chamber;

---

[4] Dr. Bruskewitz estimated the cost of operating room time to be approximately $ 20.00 per minute.

[5] Written in independent form. Ex. 113.

> a sealed, substantially fluid impenetrable enclosure surrounding said housing and defining a liquid retaining space between said enclosure and said housing, said enclosure adapted for separation from said device prior to implantation of said device;
>
> and said enclosure containing a liquid in said space with activities that substantially match the activities of the fluid in said chamber such that the mass transfer gradient across the permeable housing is insubstantial.

The other product claims add various other limitations to this structure. The method claims, claims 14-15 and 18-20, define the method of making and sterilizing a packaged fluid-containing prosthesis. Claims 18 is representative of the method claims:[6]

> A method of packaging a fluid containing prosthesis adapted to be implanted in a sterile condition, said method comprising the steps of:
>
> filling a closable permeable housing within a prosthetic device with a fluid;
>
> enclosing said prosthetic device within an enclosure which contains a liquid with activities that substantially match the activities of the fluid within the housing, thereby rendering insubstantial the mass transfer gradient across the permeable housing;

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[6] Written in independent form. Ex. 114.

> sealing said enclosure about said prosthetic device to define a sealed substantially fluid impenetrable barrier to fluid migration;
>
> enclosing said enclosure within an outer bag; and
>
> sterilizing said prosthetic device in a liquid filled state within said enclosure and said outer bag.

Initially, the PTO examiners found the Klatt invention to be obvious in view of the prior art:

> The Applicant's invention differs from Riall in view of Campbell only in the particular device he has chosen to store in the container. In as much as the basic problems of keeping the device wet while avoiding problems of osmosis are addressed and solved in Riall in view of Campbell, the Examiner views the mere substitution of one prosthesis within the package (such as a penile implant) over another as obvious to one of ordinary skill in the art.

Ex. 2 at 34. After the rejection, however, the examiners met with Mr. Klatt, his patent attorney, and an AMS official. *Id.* at 37. The examiners then reversed their earlier finding and held that the Klatt claims distinguished over prior art.

The argument that convinced the examiners is summarized in Response A to Paper No. 4:

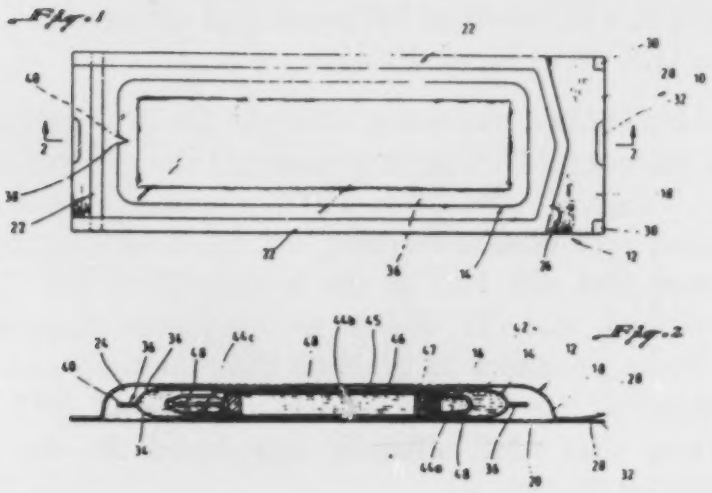
> The prior art fails to teach a packaged fluid containing prosthesis with *inter alia* a prosthetic device that includes (1) a closed permeable housing

defining a fluid containing chamber together with (2) an enclosure containing a liquid with activities that substantially match the activities of the fluid within the chamber such that the mass transfer gradient across the permeable housing is insubstantial, as set forth in pending independent claim 1. In such an arrangement it is possible to precisely engineer or control the volume of fluid in that chamber despite the ability, under atmospheric or other conditions, for the fluid to move through the walls of the housing. This is clearly a problem which was neither recognized or solved by any of the prior art of record.

Ex. 2 at 39.

The Klatt patent issued on July 1, 1986. (Figure D).[7]

Figure D

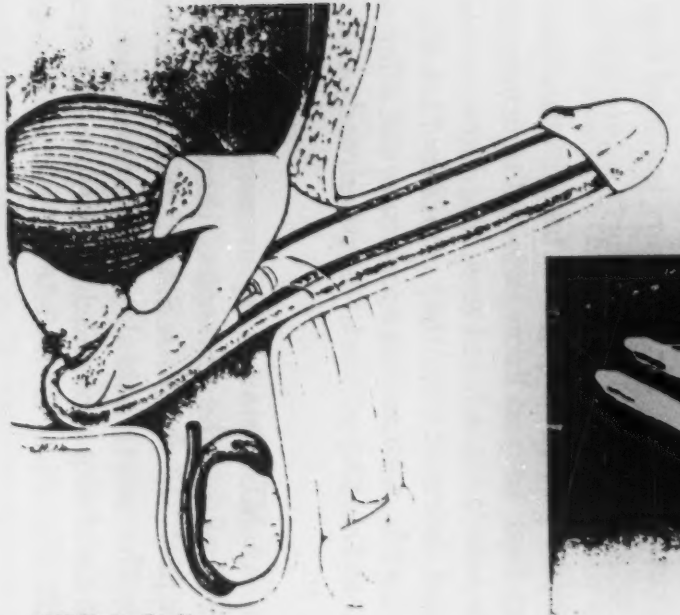


[7] Figure D appears in Exhibit 1.

V. MEC's Activities

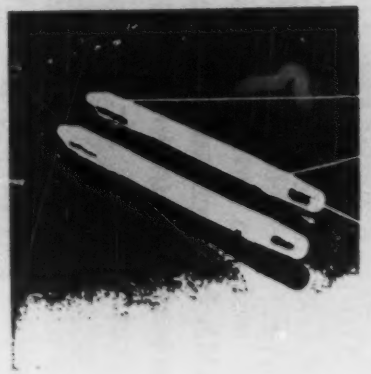
At least as early as April 1984, MEC intended to market a prefilled and sterile Flexi-Flate and (Tr. 1156-57) in early October 1984, MEC assigned the project to senior project engineer Jay Goldberg. (Tr. 1156-57, Ex. 962). Mr. Goldberg's personal project notebook indicates that the earliest packaging configurations for the prefilled and sterile Flexi-Flate utilized a rigid, vapor impermeable tube. The earliest configuration was to place the prefilled prosthesis into a tube surrounded by saline of the same osmolarity as that in the device. The tube was then capped. The inner tube was then enclosed in a slightly larger tube or pouch. (Ex. 116 at Bates 101400). In March 1985, Garry Carter, MEC's vice president of scientific affairs asked Mr. Goldberg to fill out an invention record for this configuration. (Ex. 116; Tr. 272, 277). Nevertheless, as of May 1985, an MEC product definition for the prefilled Flexi-Flate reversed the relationship of the pouch and tube; the prosthesis was to be placed in a saline-filled foil pouch and enclosed in a rigid tube. (Ex. 48 at Bates 105482).

Also in May, like many others in the urological products industry, Mr. Goldberg attended the annual American Urological Association (AUA) meeting. This is a significant professional meeting, attended by between one quarter and one half of the urologists in the United States each year. (Tr. 488) As a consequence manufacturers make an effort to promote their newest urological products at the meeting. It was at the May 1985 AUA meeting that AMS officially introduced the wet pack Hydroflex (Figure E).



AMS Hydroflex™ Self-Contained Penile Prosthesis

Squeezing the inflation pumps in the head of the penis a number of times inflates the AMS Hydroflex™ Self-Contained Penile Prosthesis. Compressing the deflation valves behind the head of the penis deflates the prosthesis to a concealable position.



rear reservoir

deflation valve

inflation pump

Figure E

This new product, the first prefilled and sterile self-contained prosthesis to reach the market, was received with great interest. The AMS booth received substantial traffic, both from urologists and (not surprisingly) from the competition. (Tr. 312, 488-89). Mr. Goldberg visited the booth. While he was there, he learned that AMS' packaging concept utilized a saline filled inner pouch containing the prosthesis, surrounded by a larger outer pouch. (Tr. 310-12). He reported his findings to MEC's R & D and marketing departments upon returning to the office. (Tr. 313).

Since AMS had beaten MEC to the punch on prefilling, there was pressure to get the prefilled Flexi-Flate into the market. (Tr. 312). Mr. Goldberg testified that following the AUA meeting, MEC's efforts intensified:

> We identified this prefilling as a feature that was necessary that we, you know, wanted to come out with. We saw it introduced and, you know, we—we decided there was another company that has come out with, we need to accelerate our efforts to speed up the project that we had already been working on.

(Tr. 402-03). An MEC marketing memo from May 31, 1985 similarly reflects the urgency of the situation: "We must have a prefilled device A.S.A.P." (Ex. 50 at Bates 106029). For the next several months after the AUA meeting, Mr. Goldberg continued to work on tube packaging concept. (Ex. 963; Tr. 315-16). Tests were run on the various configurations. The results did not prove promising: pouches blew open under the pressure of the autoclave; pouches in tubes developed holes during autoclaving; the tubes leaked due to the inability to get a

good ultrasonic weld between tube and cap. (e.g., Ex. 963 at Bates 101416, 101423; Tr. 322).

On July 11, 1985 Mr. Goldberg had the good fortune to stumble across Kapak Corporation while searching for autoclavable foil pouches. During his conversation with Kapak's sales representative, she remarked that the application he had in mind sounded familiar, because a company called AMS was using Kapak's foil pouches. (Ex. 963 at Bates 101419; Tr. 317). Kapak's representative sent autoclavable foil samples to Mr. Goldberg. On July 16, Mr. Goldberg received samples of Hydroflex from the marketing department, and he inspected the packaging. (Ex. 963 at Bates 101419; Tr. 318).

Mr. Goldberg began to test the double pouch system more intensively. (Ex. 963 at Bates 101419-23). The tube concept continued to experience problems; indeed, throughout this period, and despite repeated attempts, MEC was unable to produce a single successful rigid tube prefilled Flexi-Flate. (Tr. 1253-54). On August 23, Bob Boeck, MEC product manager, decided to go with the double pouch configuration. (Ex. 963 at Bates 101423; Tr. 322-23).

The documents of record reflect that the pressure on MEC to get a prefilled product into the market place continued to mount. From an August 11, 1985 capital appropriations request: "Physicians are now starting to turn toward the use of prefilled sterile penile prostheses rather than the conventional physician-filled implant" (Ex. 63 at 2); from a September 23, 1985 capital appropriations request: "[The purchase of equipment to produce prefilled Flexi-Flate] will put MEC on a more even footing with competitors and will result in a signifi-

cant increase in projected sales" (Ex. 62); from a February 19, 1986 marketing memo authored by product manager Bob Boeck:

> In the last several months, I've attended at least three key seminars and met with 40-50 urologists (San Francisco, Portland, Los Angeles, Boston, New York, San Antonio). Based on conversations with these doctors, the following is what I see shaping up in the marketplace:
>
> 1. Increasing objection to Flexi-Flate not being prefilled. Virtually every doctor who has commented on this aspect of the Flexi-Flate has indicated it adds unnecessarily to O.R. time, which increases cost to the patient. The doctors also see our not having prefilled as an inconvenience on their part and a step which they don't have to do through if they use the Hydroflex.

(Ex. 53).

The final product definition for the prefilled Flexi-Flate, dated May 5, 1986 states that the Flexi-Flate will be shipped in a double foil pouch configuration like Hydroflex:

> An implant is filled with saline and placed into the inner pouch, with the tail at the notched end. Fifty (50) ml of saline is added to the pouch and the pouch is sealed. The inner pouch is placed into the outer pouch with the tear notches at opposite ends. .5ml of saline is added to the outer pouch and the pouch is sealed.

(Ex. 56 at Bates 105455).

VI. MEC Attempts to Patent Wet Pack Flexi-Flate

MEC sought to patent its prefilled and presterilized self-contained device. Mr. Goldberg was asked by Garry Carter, MEC's vice president for scientific affairs, to submit an invention record for the purpose of filing a patent application for a prefilled Flexi-Flate. (Ex. 116; Tr. 268-70, 272). At the time he signed his invention record, no one questioned that the idea for a prefilled Flexi-Flate was Mr. Goldberg's. (Tr. 272). The invention record described the many advantages a prefilled Flexi-Flate would have over the unfilled Flexi-Flate being sold at the time. (Ex. 116 at Bates 101401; Tr. 273, 277-82).

On February 7, 1986, with full knowledge of AMS' Hydroflex and its configuration, MEC filed a patent application for a prefilled Flexi-Flate in the name of Jay Goldberg. (Ex. 117; Tr. 415-16). The Goldberg application was assigned to MEC. (Tr. 392). The application describes the significant advantages of the prefilled device over an unfilled device. (Tr. 342-44).

When Mr. Goldberg signed the application, he believed that he was the original and sole inventor and he was not aware of any material prior art. (Ex. 117; Tr. 339-42). Mr. Goldberg further believed at the time he filed his patent application that the combination of a double pouch and a prefilled self-contained inflatable penile prosthesis, with fluid in the pouch to keep fluid from coming out of the device, was new. (Tr. 396-97). When MEC's attorney prepared the application, it was reviewed by at least Mr. Goldberg, and MEC's attorney expected Mr. Goldberg to sign and the PTO to examine the application with the claims as filed. (Tr. 1373, 1376-80).

MEC and its attorneys fully participated in the selection of the prior art to be disclosed to the PTO. (Tr. 355-56). MEC's attorney was experienced and familiar with the prior art. (Tr. 1368-69, 1380-82).

MEC has suggested that the Goldberg patent application was limited to the use of a rigid tube or "non-expandable" outer enclosure, but this argument is unconvincing. The Goldberg application plainly teaches that a flexible double pouch can be used. (Tr. 348-53, 387-91). Both Mr. Goldberg and Mr. Carter, who was also involved in the Goldberg application, each admitted that claim 3 of the Goldberg application would cover AMS' Hydroflex. (Tr. 352-53, 414).

The PTO issued a restriction on MEC's application, requiring the attorney of record, Mr. Kryshak, to elect which invention he wished to pursue. He elected to proceed with claims 1, 2, 11 and 12. In February 1987, the PTO issued its first office action, which rejected claims 1 and 2 "as being unpatentable over Klatt in view of Lloyd." Claims 11 and 12 were rejected "as being clearly anticipated by Klatt." (Ex. 117 at 49). Thereafter, the application was abandoned. (Tr. 1387-88).

VII. Validity of the Klatt Patent

A patent shall be presumed valid, and each claim shall be presumed valid independently of the other claims. 35 USC 282. The burden is on the party asserting invalidity to prove it with facts supported by clear and convincing evidence. *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 872 (Fed. Cir. 1985).

The presumption of validity is premised on the expertise possessed by the Patent and Trademark Office interpreting the references and having familiarity with the level of ordinary skill in the art. *Bausch & Lomb, Inc. v. BarnesHind/Hydrocurve, Inc.*, 796 F.2d 443, 447 (Fed. Cir. 1986), *cert. denied*, 484 U.S. 823, 108 S. Ct. 85, 98 L. Ed. 2d 47 (1987). The deference accorded to the PTO's expertise is heightened where the prior art before the court is the same as that before the PTO. *Id.*

MEC contests the presumptive validity of the patent on the grounds that the invention was obvious from the prior art. 35 USC 103. The ultimate conclusion of obviousness is one of law, but the conclusion is based on the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 86 S. Ct. 684, 693, 15 L. Ed. 2d 545 (1966): 1) the scope and content of the prior art; 2) the difference between the prior art and the claims at issue; 3) the level of ordinary skill in the pertinent art at the time the invention was made; and 4) the objective evidence of nonobviousness, such as commercial success, satisfaction of a long-felt need, failure of others, recognition by the industry, and copying.

As the court embarks upon its obviousness inquiry, it is instructive to keep a recent caution by the Federal Circuit in mind:

> The obviousness standard, while easy to expound, is sometimes difficult to apply. It requires the decisionmaker to return to the time the invention was made. The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time. . . . That which may be made clear and thus 'obvious'

> to a court, with the invention fully diagrammed and aided by experts in the field, may have been a breakthrough of substantial dimension when first unveiled.

Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1050-51 (Fed. Cir. 1988).

A. Scope and Content of the Prior Art

The scope of the prior art is that art which is reasonably pertinent to the particular problem with which the inventor was involved. *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 722 F. Supp. 595, 605 (N.D. Cal. 1989) *citing In re Deminski*, 796 F.2d 436 (Fed. Cir. 1986). The scope of the prior art would include methods and materials used in medical and food packaging.

MEC's expert on the question of obviousness, Dr. James Goff, stated that he found the following prior art to be the most relevant to whether the Klatt patent was invalid for obviousness (Tr. 1939-40): 1) the Banko patent (Ex. 854) combined with the Mazzocco patent (Ex. 889); 2) the Naficy patent (Ex. 751); 3) the "suture" patents, Riall (Ex. 3) and Rynkiewicz (Ex. 507); 4) the canning and pickling of food (Tr. 1939-40); 5) Dr. Austad's patent, publication (Ex. 899), and experiments with tissue expanders.

The Banko patent teaches a method and apparatus for implanting a fluid-filled replacement lens in the human eye. The lens is to be made of a deformable "suitable plastic material" such as for example used in soft contact lenses; it is not apparent whether this material

is permeable or not. The lens may be filled with a sterile solution, gelatin, or plain or Ringers saline solution. (Ex. 854 at col. 2). Banko does not teach that the implant is to prefilled and presterilized by the manufacturer. (Tr. 1933). The Mazzocco patent teaches, among other things, an improved method of packaging an intraocular lens such that the optical parameters of the lens could be viewed from outside the bottle. A screw top bottle made of glass, stainless steel, titanium, or polymeric material such as silicone rubber is used; it is filled with a "suitable fluid" such as saline, distilled water, or alcohol. The lens is suspended from a holder affixed to the cap. The result is designed to be autoclavable. (Ex. 889 at col. 4 lines 25-28, col. 6 lines 45-65, and col. 7 lines 29-35).

The Naficy patent is formally titled "Breast Prosthesis with a Biologically Absorbable Outer Container." As its name suggests, the patent teaches a breast prosthesis comprised of an inner core of biologically acceptable material surrounded by silicone rubber sac in the preferred embodiment. The inner core is in turn surrounded by an outer sac made of biologically absorbable material; there is saline between the inner and outer membranes. The whole unit is implanted, and with time the outer membrane is absorbed into the body.

For present purposes, there is no material differences between the two suture patents. (Tr. 1967-68). Mr. Klatt cited the Riall patent in his application. In Riall, the sutures are packaged in an inner envelope which is enclosed in two more envelopes, each envelope nested inside the other. The interior envelope may contain the sutures dry or in a conditioning liquid. Sutures which require a conditioning liquid are packed in ethyl alcohol, or

a mixture of ethyl alcohol, isopropyl alcohol, and water, or some other conventional conditioning liquid. In the Rynkiewitz patent, the suture is packed in a packet containing conditioning liquid such as methanol or ethanol. This packet is in turn packaged in another, larger packet.

Dr. Goff also claimed that he found the canning and pickling of food to be relevant. He testified that in canning, the food item—he used the example of green beans—is blanched in hot salt water. This process purges the gases from the bean, densifies it, and fills the bean with blanching fluid. The beans are then put in a can, the headspace is purged to remove excess air, and a lid is put on. The can is then placed in a pressure vessel and subjected to a steam cooking process. (Tr. 1864-65). Dr. Goff stated that the scientific principle involved in the blanching process was osmosis. *Id.*

Dr. Goff also testified that he found the patent and work of Dr. Austad to be relevant. Dr. Austad has a patented tissue expander which is of record in this case. (Ex. 503). The patent teaches a surgically implantable device for expanding skin and mucous tissue. The device involves the use of a partially collapsed sealed envelope formed from a material which is permeable to extracellular body fluid, such as silicone. The envelope contains a material which establishes an osmotic potential across the envelope wall, such as dry sodium chloride. Body fluid crosses the membrane to fill the envelope. As the envelope fills it expands the adjacent tissue. There is no disclosure in the patent or Dr. Austad's publication (Ex. 899) of preparing or shipping *prefilled* implants which are *then* implanted in the body.

Dr. Goff also found Dr. Austad's post-experiment storage of tissue expanders to be relevant. Basically, Dr. Austad testified that he would store the filled tissue expanders in jars of saline. For the most part, the salt concentration in the saline initially differed from that in the tissue expander. (Tr. 1585). However, Dr. Austad also testified that he performed one experiment where the tissue expander had much more than an isotonic amount of saline inside. To store these implants, saline plus additional sodium chloride crystals were poured into the jar; as a result, the salt concentration inside the implant and outside the implant was the same. (Tr. 1585-86).

Dr. Austad also testified that his experiments were "essentially" accessible to the public. (Tr. 1588). He said various people including students, surgeons, drug representatives and the like passed through his laboratory. But it became clear to the court on cross examination that while various persons may have entered Dr. Austad's lab, the concept of how the filled tissue expanders were stored was not public. For one thing, persons having access to the lab would not know the import of the jars until someone explained it to them. (Tr. 1624). Certainly, Dr. Austad did not go out of his way to point it out to visitors. Indeed, Dr. Austad stated that he could not remember anybody inquiring into the specifics of this storage method. (Tr. 1623). Consequently, the court does not find Dr. Austad's experiments to be prior art for purposes of 35 USC 102.

The court observes that even if it were to consider the jars to be prior art, there would be a number of reasons why they do not render Klatt's invention obvious to a person of ordinary skill in the art. First, the jar experi-

ment is not a packaged prosthetic device intended to be implanted. The devices were in jars for testing purposes, not as future implants. Second, the only sterilization Dr. Austad recalled involved sterilizing *explanted* devices, not devices filled and intended for implantation. In addition, the Austad implants were sterilized in open beakers, not the jars or any other "package." (Tr. 1592, 1609-10). In any event, the jars could not maintain sterility, even were it possible to sterilize them. Third, except for one experiment, Dr. Austad frankly admitted that in his "jar experiments", he did not achieve any osmotic balance between the devices and liquid in which they were placed without an initial mass transfer gradient between the device and the liquid in the jar.

B. Level of Ordinary Skill in the Art

Factors that may be considered in determining level of ordinary skill in the art include: 1) the education level of the inventor; 2) type of problems encountered in the art; 3) prior art solutions to those problems; 4) rapidity with which innovations are made; 5) sophistication of the technology; and 6) educational level of active workers in the field. *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1381-82 (Fed. Cir. 1983). Not all such factors are present in every case, and one or more may predominate in a particular case.

A second formulation of the person of average skill in the art:

> The person of average skill in the art, under sec. 103, who is the patent law equivalent of the reasonable man in tort law, is neither a genius nor

> an expert, and he is not expected to think entirely in terms of theoretical, physical principles, but is much more likely to be motivated by more mundane considerations, such as the practical functional use of prior art devices.

Ciba-Geigy, Ltd. v. Tenatek, 202 USPQ (BNA) 669, 674 (N.D. Miss. 1978).

Regardless of the formulation used, the important consideration lies in the need to adhere to the statute. The court must hold that an invention would or would not have been obvious, as a whole, when it was made, to a person of "ordinary skill in the art"—not to the judge, or to a layman, or to those skilled in remote arts, or to geniuses in the art at hand. *Environmental Designs v. Union Oil Co. of California*, 713 F.2d 693 (Fed. Cir. 1983).

The relevant time frame is 1983-84. The court finds the testimony of Dr. Goff and Donald Barcan relevant to the resolution of this issue. Dr. Goff testified that the person with ordinary skill in the art would have a technical degree and two or three years of experience in the design of packages for medical devices. (Tr. 1861). On cross examination, he admitted that the most salient training for the packaging field occurs on the job. Similarly, he stated he would not be surprised if there were persons involved in designing packages who had no college education. (Tr. 2021).

Donald Barcan is a packaging engineer called to testify by AMS. He testified that in the 1960s—the infancy of sterile medical device packaging technology—the skill level required to package medical devices was

low. "It might have been a glass syringe, for example, and it went into a box and that box might have been wrapped with tissue." (Tr. 2239). Not surprisingly, persons assigned to package devices usually had no more than a high school education. As the technology associated with medical device packaging became more sophisticated, these persons were not replaced. However, the technical education of incoming packaging personnel began to increase, and through attrition, the educational training of persons skilled in the art began to change. By 1983-84, approximately one third of persons skilled in the art had college degrees. (Tr. 2237-40).

The court also observes that while both William Klatt and Jay Goldberg had technical degrees, neither had any prior experiences in packaging medical devices.

Given the testimony, the court finds that the person of ordinary skill in the art in 1983-84 would have either had a college degree and several years of experience in the medical device packaging field, or would have had no college degree but would have had five to fifteen years experience in the medical device packaging field.[8]

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[8] The court does not find either Professor Goff or Mr. Barcan themselves to be of ordinary skill in the art; each of them is more highly skilled than the person of ordinary skill. Obviously, that does not mean that the court refuses to consider what they say the person of ordinary skill knows; it only means the court may not look to them as "living examples" of persons with ordinary skill.

C. Differences Between the Prior Art and the Claims at Issue

Mr. Klatt's invention involves a packaged fluid-filled device containing a defined amount of fluid in a semi-permeable housing, and methods of packaging and sterilizing it. The testimony did not disclose that the concept of prefilling and presterilizing a device by the manufacturer existed in the prior art. For example, Banko does not establish this. Professor Goff admitted that Banko does not teach that the lens is to be packaged prefilled and presterilized at the manufacturer. (Tr. 1932-33; *see also* 2259). Nor does the combination of Banko combined with Mazzocco establish this. Neither, according to Dr. Goff, does Naficy teach this particular concept. (Tr. 1934). And the court is simply not convinced that Dr. Austad's patent or jar experiments establishes this. His patent indicates that the implants were intended to be implanted dry; the concept behind his tissue expander was to allow the filling of the device to occur gradually, making the stretching of the tissue less painful. His jar experiments, to the extent they can be considered prior art, were with explanted devices which had filled during their stay in the body of an animal; they were not intended to be reimplanted in that form.

The court also finds there is no prior art showing any packaged medical device containing a defined amount of fluid in a permeable membrane. (Tr. 2026). Dr. Goff admitted that Mr. Klatt designed a product that was filled with a precise amount of fluid by the manufacturer. (Tr. 1936-37). It was then packaged and the package was sterilized. (*Id.*). The critical amount of fluid in the device survived the packaging and sterilization. (*Id.*). Thereaf-

ter, the critical amount of fluid and sterility remained inviolate and survived handling, transport, and lengthy storage so that it was "ready-to-go" during surgery. (*Id.*). And this, Dr. Goff admitted, "no one had ever done before." (Tr. 1937).

Similarly, there is no prior art showing the use of osmotic principles for purposes of packaging and sterilizing any product, much less a medical device. (Tr. 2254). Sutures, as well as packaged bandages, sponges, and soft optical lenses, simply absorb the liquid in the package until they are saturated. There is no need or ability to control the amount of fluid in the materials. (Tr. 1970). In short, these patents merely provide a mechanism by which these items can be kept moist. On the other hand, the Klatt invention involves a device with a critical amount of fluid in a semi-permeable housing, where the fill volume is maintained by controlling the osmolality of the solution inside and outside the device. Analogously, the suture packages do not need to be completely filled with fluid because they are conditioning liquids. Klatt requires substantially complete filling, because air in the enclosure may cause bubbles to permeate the device, causing it to lose critical filling volume. (Tr. 1972-73).

If food packaging and canning is considered prior art, it is no more pertinent than the prior art found in the Campbell patent (Ex. 7) or the Riall patent (Ex. 3) which were considered by the PTO. The canning process described by Dr. Goff included "blanching" the vegetable, placing it in a can, and then closing it. (Tr. 1944-49). In the can, however, the vegetable is saturated with the filling solution and absorbs the fluid around it. There is no way to control how much liquid the food absorbs. (Tr. 1948-53).

Finally, Mr. Klatt's invention was the first time an autoclave process was used with a packaged penile prosthesis. (Tr. 1956).

D. Secondary Considerations

It is jurisprudentially inappropriate to disregard any relevant evidence on any issue in any case, patent cases included. Thus evidence rising out of the "secondary considerations" must always be considered when present, before any determination on the obviousness question is rendered. It is to be considered as part of all the evidence, not just when the court remains in doubt after reviewing the art. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983).

Evidence of secondary considerations may establish that an invention appearing to have been obvious in light of the prior art was not. *Id.* The principal secondary considerations which support findings of non-obviousness are: a) commercial success; b) long-felt but unsolved need; c) failure of others; and d) copying of the claimed invention.

1. Commercial Success

The court finds the Hydroflex was a commercially successful product. From its introduction at the May 1985 AUA meeting, the product enjoyed very good sales, though beginning in 1987 demand for the product has steadily declined. The evidence reflects that in 1985 AMS sold 3,336 Hydroflex units for total dollar sales of $7,665,142.00; in 1986 AMS sold 7,698 Hydroflex units

for total dollar sales of $17,211,040.00; and in 1987 AMS sold 4,809 Hydroflex units for total dollar sales of $13,105,847.00. (Ex. 107).

2. Longfelt But Unsolved Need

Against the backdrop of other patent cases the court has examined, the length of time the urological products industry went without a prefilled and sterile packaged penile prosthesis is not especially long. *See e.g.* 2 D. Chisum, *Patents*, sec. 5.05[1] at 5-398 to 5-399. Approximately eight months elapsed between MEC's introduction of its dry pack Flexi-Flate (October 1984) and AMS's introduction of the Hydroflex (May 1985). There is no evidence of any other company's efforts to prefill a penile prosthesis.

3. Failure of Others and Copying

During the time Mr. Klatt was working on the prefilled Hydroflex, MEC was also working on its prefilled product but without success. Mr. Goldberg then saw the Klatt invention the 1985 AUA meeting and began considering the double pouch system more seriously. In the court's opinion it was no mere coincidence that MEC began to work intensively with the double pouch system shortly after seeing Klatt's invention at the AUA.

The court further observes that, as elaborated at length above, MEC attempted to patent a prefilled product which falls literally within the scope of claims 1-12, 14-15, 18-20, and 20-24 of the Klatt patent.

D. Conclusion on Obviousness

Mr. Klatt's invention is a packaged penile prosthesis and method composed of, respectively, multiple components and multiple steps. All these interact to provide a particular kind of surgical prosthesis with suitable intraoperative characteristics. The invention as a whole is that product, with its packaged form, and its advantages, benefits and properties. It is the combination which is novel and is the subject of the claims of the Klatt patent. (Tr. 1081).

That all elements of an invention may have been old is not unusual, and indeed, irrelevant. Virtually all inventions are combinations and virtually all are combinations of old elements. A court must consider what the prior art as a whole would have suggested to one skilled in the art. *Environmental Designs*, 713 F.2d at 698. The court is unable to accept MEC's contention that the claims of the Klatt patent would have been obvious to a person of ordinary skill in the art at the time of Klatt's invention. It appears to the court that MEC has used the Klatt patent as a roadmap for finding prior art, and had then attempted to combine that prior art with the hindsight afforded by it knowledge of Mr. Klatt's invention; this appeared especially to be true in the case of Dr. Goff's testimony.

For example, MEC's main argument is that Klatt is rendered obvious by combining Banko and Mazzocco. (Tr. 1975). Yet there is nothing in the prior art of record which would invite or suggest to a person of ordinary skill in the art that the two references be combined. That combination can only be made by hindsight reconstruction using Klatt as a roadmap. The only reason Dr. Goff

could give for attempting to combine Banko with Mazzocco was a two pronged "leap of faith" (Tr. 2000) that: 1) Banko would be filled at the manufacturer and be shipped prefilled and sterile; and 2) Mazzocco was the only way of doing it. However, Banko does not disclose how or where his lens is filled or how it is implanted. (Tr. 2246). Even Dr. Goff admitted this. (Tr. 1989). Because there is no suggestion in the art that a Banko lens would be shipped prefilled, there is no incentive or motivation for anyone to combine it with a fluid-filled packaging system such as Mozzocco.

It also appears that there is a reason why those with ordinary skill in the art would not combine Banko and Mozzocco, namely that the Banko and Mozzocco lenses function differently. Mozzocco's lenses do not change shape in the eye. (Tr. 1985; 2247-48). It maintains the same optical properties at all times. On the other hand, the Banko lens is designed to be sutured to muscles in the eye. Then, as the muscles moved, the lens would change its shape and optical properties. (Ex. 854, col. 3; Tr. 1984, 2247-48). The differences are relevant because the point of Mozzocco is to provide a container and fixture whereby the optical properties of a fixed lens can be measured. (Tr. 2247-48; 2261). The Banko lens is not of a type for which the Mozzocco container was designed; the optical properties of the Banko lens are not fixed and change when sutured to the eye muscles. Consequently, there is no motivation for one skilled in the art to combine the two patents.

MEC has not shown anything in the prior art that suggests the particular combination of elements needed to produce Klatt's invention. An invention must be

viewed as a whole, and MEC's prior art does not suggest in any way or motivate one skilled in the art to make the Klatt invention as a whole.

After becoming aware of the issuance of the Klatt patent, MEC engaged in numerous world-wide searches. (Ex. 118). Yet despite all of this extensive searching, MEC has not found any references which describe the unique combination claimed in the Klatt patent. MEC plainly believed that this subject matter was new and nonobvious as evidenced by the filing of its own patent application on the subject matter and failing to cite any of the prior art upon which it now relies to invalidate the Klatt patent.

VIII. Damages

Since the court has determined that the Klatt patent is not invalid for obviousness, and MEC has stipulated that its Flexi-Flate prosthesis would infringe upon such a finding, the court must consider the amount of damages to which AMS is entitled. AMS claims that it is entitled to lost profits for the period of July 1, 1986 (the date the Klatt patent issued) through December 1987 (MEC's noninfringing "vacuum pack" Flexi-Flate entered the market in January 1988) because, but for MEC's infringement, AMS would have made the sales that were made by MEC for its wet pack Flexi-Flate. From January 1988 AMS claims a reasonable royalty, since during this period MEC was principally selling the "vacuum pack" Flexi-Flate (which AMS no longer accuses of infringement), but also continued shipping its remaining inventory of the wet pack Flexi-Flates.

The applicable statutory authority governing the amount of damages is 35 USC 284, which provides in pertinent part:

> Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

The United States Supreme Court, in interpreting this statute, has defined damages as "compensation for the pecuniary loss the patent owner suffered from the infringement, without regard to the question whether the defendant has gained or lost by its unlawful acts." *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 507, 84 S. Ct. 1526, 12 L. Ed. 2d 457 (1984).

There are two different approaches toward determining the measure of damages in patent infringement cases. *Hartness Int'l v. Simplimatic Engineering Co.*, 819 F.2d 1100, 1112 (Fed. Cir. 1987). The first approach, the lost profits method, is used when the record permits an accurate determination of the patentee's loss. *Hanson v. Alpine Valley Ski Area, Inc.*, 718 F.2d 1075, 1078 (Fed. Cir. 1983). The second approach, employed when actual lost profits cannot be determined, is to award damages on the basis of a reasonable royalty. *Id.*

A. Lost Profits

Pursuant to 35 USC 284, "the general rule for determining the actual damages to a patentee that is itself

producing the patented item is to determine the sales and profits lost to the patentee because of infringement." *Del Mar Avionics v. Quinton Instrument Co.*, 836 F.2d 1320, 1326 (Fed. Cir. 1987). To obtain lost profits, a patent owner must prove causation; that is, that " 'but for' the infringement, the patent owner would have made the sales the infringer made." *Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1065 (Fed. Cir. 1983); *Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp.*, 739 F.2d 604, 616 (Fed. Cir.), *cert. denied*, 469 U.S. 1038, 105 S. Ct. 516, 83 L. Ed. 2d 405 (1984).

"In proving his damages, the patent owner's burden of proof is not an absolute one, but rather a burden of reasonable probability." *Lam*, 718 F.2d at 1065. The patent owner need only prove that there is a reasonable probability he would have made the infringing sales. *Paper Converting Machine Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 21 (Fed. Cir. 1984). "The determination of damages is not an exact science and 'the amount need not be proven with unerring precision.' The trial court is required to approximate, if necessary, the amount to which the patent owner is entitled." *Del Mar Avionics*, 836 F.2d at 1327. In addition, "the patentee is not obligated to negate every possibility that a purchaser might not have bought the patentee's product instead of the infringing one, or might have foregone the purchase altogether." *Id.* at 1326; *Datascope Corp. v. SMEC, Inc.*, 879 F.2d 820, 826 (Fed. Cir. 1989).

A patent owner may obtain lost profits by meeting the standard set forth in *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978):

> To obtain as damages the profits on sales he would have made absent infringement, i.e., the sales made by the infringer, a patent owner must prove: (1) demand for the patented product, (2) absence of acceptable noninfringing substitutes, (3) his manufacturing and marketing capability to exploit the demand, and (4) the amount of profit he would have made.

Id. at 1156. A patentee is not entitled to lost profits if it fails to establish any of the above requirements. *Smithkline Diagnostics v. Helena Laboratories*, 926 F.2d 1161, 1165 (Fed. Cir. 1991). The patent owner must convince the court that it has met each of these elements to a reasonable probability.

MEC does not dispute that there was a demand for the patented product (although it argues that demand did not result from the patent). The court independently finds that there was demand for the patented product, and that demand resulted in substantial part from the characteristics of the patented product. (Tr. 815-16, *see also* MEC Response para. 58). Similarly, MEC does not dispute that AMS had the ability to exploit the demand for the product. The court similarly finds that AMS had the ability to exploit demand for the product. (Tr. 816; Ex. 106).

Central to whether there were "acceptable noninfringing substitutes" for the Hydroflex is the definition of that term. In the recent case *Kaufman Co., Inc. v. Lantech, Inc.*, 926 F.2d 1136 (Fed. Cir. 1991), the Federal Circuit offered the following guidelines for determining if any exist.

> To be deemed acceptable, the alleged acceptable noninfringing substitute must not have a disparately higher price than or possess characteristics significantly different from the patented product.
>
> . . .
>
> "A product lacking the advantages of that patented can hardly be termed a substitute acceptable to the customer who wants those advantages."

Id. at 1142-43 (emphasis in original), *quoting TWM Mfg. Co., Inc. v. Dura Corp.*, 789 F.2d 895, 901 (Fed. Cir. 1986). Nevertheless, "if the realities of the market are that others would likely have captured sales made by the infringer, despite a difference in the products, it follows that the 'but for' test is not met." *SmithKline Diagnostics v. Helena Laboratories*, 926 F.2d 1161, 1166 (Fed. Cir. 1991).

MEC has urged that the court must consider all impotence treatments, including drug therapy, rods, and multi-component inflatables as acceptable noninfringing substitutes for the Hydroflex. Yet the evidence clearly convinces the court otherwise. The salient characteristics of the Hydroflex are that it provided good flaccidity and rigidity without the more invasive surgery necessary to implant the multi-component device.[9] (Tr. 80-81). In

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[9] MEC suggests that the OmniPhase and DuraPhase mechanical protheses should be classified in the self-contained market. Dacomed first introduced the OmniPhase in August 1986 (Ex. 29), and it had such immediate and major problems that the OmniPhase was withdrawn from the market and then

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addition, as between it and the dry pack Flexi-Flate, Hydroflex came to the operating room prefilled and sterile. This was a convenience for the surgeon, but more importantly provided an added margin of safety for the patient, since prefilling with extra clean saline made the valves less prone to jamming, so the implant was less likely to require removal.

The other impotence treatments had their own individual spectrum of properties, benefits and constraints that clearly differentiated one from another making them unacceptable as noninfringing substitutes for the Hydroflex. (Tr. 80-82, 690-92, 726-32). Drug therapy was nonsurgical but was prone to causing priapism, involved sticking needles into the penis, which caused scar tissue to develop. (Tr. 60-61). The rods were inexpensive and had low incidence of malfunction, but were hard to conceal and provided only adequate rigidity for coitus. The multi-component inflatables provided the best concealment and flaccidity but involved more invasive surgery

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[9] (...continued)
reintroduced in the fall of 1987. (Ex. 29; Tr. 85-86, 228, 562). As noted by Mr. Boeck, the OmniPhase had a history of failure and cosmetic deficiencies. (Tr. 731). The DuraPhase was introduce only in September 1987. These mechanical rods consist of a series of articulating segments with a central cable holding the segments together. (Ex. 24, 28). Their function can be analogized to a gooseneck lamp. Although sometimes classified as "self-contained" devices, they are neither hydraulic nor inflatable, and they do not provide the same properties as Hydroflex or Flexi-Flate. (Tr. 86). In the 1986-87 time period, the OmniPhase and DuraPhase were beset with performance difficulties and had only a minute portion of the prothesis market. (Ex. 82; Tr. 86, 580-83, 729-32).

and had leakage and malfunction problems similar to the dry pack Flexi-Flate.

Further, the realities of the market are not such that other impotence treatments would have captured a significant amount of the sales made by the infringing wet pack Flexi-Flate, despite a difference in the products. In this regard, the court found the testimony of Drs. Bruskewitz and Latham most convincing. Dr. Bruskewitz, an implanting urologist and a highly credible witness, explained how he and other implanters typically explained the options available to patients:

> When it comes to the treatment itself, we have a discussion with the patients about all the various options in some detail. It's often a lengthy discussion, sometimes two discussions in which we spell out the treatment options; psychological therapy, drug injections, vacuum devices, penile implants. And we try and be as detailed as reasonably possible so that the patient is a part of the decision.

(Tr. 63). If the doctor and patient agreed that an implant appeared to be the treatment best suited to the patient, a number of factors specific to devices were discussed, including reliability, concealability, cost, ease of insertion, manual dexterity necessary to operate, and degree of rigidity. (Tr. 90-91). Sometimes after the discussion the patient elected no treatment. (Tr. 77). More often, the patient and doctor would decide upon a device after weighing the advantages and disadvantages of the various implants.

The court finds that those who chose the Hydroflex or the infringing wet pack Flexi-Flate did so after careful deliberation; recognizing the unique set of advantages and disadvantages presented by that particular type of device.[10] They were attracted to it by its good flaccidity and rigidity (better than the rods but not as good as the multicomponent), less invasive surgery (a factor with the multicomponent), and the fact that prefilling made the device less prone to malfunction (a factor with the multicomponent and the dry pack Flexi-Flate). The patients who selected the self-contained inflatable would not have chosen a different type of device had the wet pack Flexi-Flate not been on the market.

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[10] The court also finds that patients did not have the option of choosing directly between Hydroflex and Flexi-Flate. In performing implant surgery, it was desirable to always have a backup device available. This required hospitals to stock two units in each size for each type of device. The cost of such stocking was very high. As a result, implanters typically offered (and the patient typically had the choice of) only one brand for each type of device. For example, a hospital might stock the MEC Flexi-Rod as its brand of rod, the Mentor device as its brand of multi-component, and the AMS Hydroflex or the MEC Flexi-Flate (but not both) as its brand of self-contained unit. (Tr. 97-99).

As a result of the patient's options being restricted to choosing the *type* of device, as opposed to also choosing the brand within the type, the court rejects MEC's argument that patients would or could choose a self-contained device based on their preference for its operating characteristics. Simply put, the court finds that patients did not have the option of choosing MEC's spontaneous deflation-prone Flexi-Flate over AMS' Hydroflex, which was difficult to deflate, "because it's more natural anyway." (Tr. 888).

The court also found Dr. Latham's testimony helpful on the issue of availability of noninfringing substitutes. Dr. Latham is a professor of economics specializing in quantitative microeconomics, the quantitative study of how individual firms, households and persons decide how to spend their limited resources. Dr. Latham posited that the only way to accurately measure people's preferences for the relative advantages and disadvantages of various products during a historical period, in this case 1985-87, was to examine their purchasing choices, as reflected by market data. (Tr. 845-49). Using this method, Dr. Latham concluded that 1) self-contained inflatables are a submarket within the larger impotence products market (Tr. 822-25); and 2) the dry pack Flexi-Flate was not a serious competitor in this market once AMS was able to overcome the backorder problem with the Hydroflex. (Tr. 797-812, 824, 860-66). Dr. Latham's testimony was very credible, and the court finds that it supports the conclusion that a noninfringing substitute for the Hydroflex did not exist.

After hearing his testimony, observing his demeanor and studying his survey data, the court must to reject the conclusions of MEC's economist, Dr. Lewis Solmon. Dr. Solmon conducted a survey of urologists in 1990 which attempted to demonstrate the "decision process underlying the choices *by urologists* of particular penile prosthetic devices." (Ex. 1015 at 2). The survey, however, is seriously flawed in many respects and as a consequence fails to convince the court of the availability of acceptable substitutes in the penile implant market in 1986-87.

Flaws in the survey include the following. First, the court has serious doubts about whether it is possible to survey in 1990 the preferences of persons in 1986-87 with any degree of accuracy. In this regard, the court chooses to credit Dr. Latham's assertion that it is poor technique for an economist to utilize a survey to obtain the preferences of consumers. Second, the survey fails to address the reality that the patient and the physician choose the particular type of implant together. As was clear from the testimony of Dr. Bruskewitz and the other urologists, the patient had substantial input into which device was appropriate for his lifestyle. Third, to the extent that it would be appropriate to study urologists, Dr. Solmon did not study the appropriate population of urologists, namely actual implanters of penile protheses active in 1986-87. (Tr. 2157-62, 2173-74). Fourth, the response rate to the survey of about six percent was well below acceptable limits, and no post-survey attempts were made to determine how representative the respondents were of the total relevant population. (Tr. 2155, 2165-77, 2180-82). Fifth, the terms used and the questions asked were not pretested and were in many instances confusing, overlapping and uncertain in meaning, particularly regarding terms like "consider" and "packaging." (Tr. 2154, 2184-97; see also 1806-08, 121). Sixth, Dr. Solmon was inexperienced in conducting surveys of this nature. (Tr. 2156). Seventh, no evidence was presented regarding the mailing, receipt, coding or accuracy of the data. (Tr. 2156). Eighth, the survey was mailed to the same population twice, with no care taken to avoid multiple responses from the same doctor. (Tr. 2182-83).

Finally, the court turns to the question of whether AMS has proved the amount of profit it would have made on each of the Hydroflex units it would have sold but for the sale of the infringing Flexi-Flate. The court concludes, based on the lengthy testimony of Dr. Latham, the deposition testimony of AMS controller Robin Cleveland, and documents prepared by AMS, that AMS would have obtained incremental income of $2,072 for every additional unit of Hydroflex that it would have sold in the United States, and $888 for every international sale during the period July 1, 1986 to December 31, 1986. The court further finds that during 1987, the AMS would have enjoyed an incremental income of $2,266 for every additional Hydroflex it sold in the United States and $832 for every international sale. (Ex. 100, 112; Tr. 812, 817-21, 836, 918-99). MEC has presented no evidence to suggest that AMS' incremental profit calculations are incorrect. Thus, the lost profits to which AMS is entitled may be calculated by multiplying the per unit incremental profit times the number of infringing sales made during the relevant time period.

B. Patent Marking

MEC claims AMS may only recover limited damages for two reasons. First, MEC claims AMS failed to mark the Hydroflex with the word "patented" until long after the patent issued. In addition, MEC claims that AMS never provided "notice" of the claimed infringement until this lawsuit was filed on October 28, 1987. As a result, MEC claims it is only liable for damages from the date of filing.

The Patent Act imposes on patent owners a duty to mark patented articles. 5 D. Chisum, *Patents*, sec. 20.03[7][c] at p.20-249. However, where a patent claims only a method (as opposed to a product, or a method and a product) there is no duty to mark. *Bandag, Inc. v. Gerrard Tire Co., Inc.*, 704 F.2d 1578, 1581 (Fed. Cir. 1983) *citing Wine Railway Appliance Co. v. Enterprise Railway Equipment Co.*, 297 U.S. 387, 56 S. Ct. 528, 80 L. Ed. 736 (1936). This is not surprising since one cannot mark an abstraction. A somewhat more problematic question is whether there is a duty to mark when the patent contains both product and method claims. In *Devices for Medicine v. Boehl*, 822 F.2d 1062 (Fed. Cir. 1987), the court indicates that where there are both product and method claims being claimed infringed, the patentee must mark the product.[11] This is consistent

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[11] The *Devices for Medicine* court stated:

> In *Bandag*, and in *Hanson [v. Alpine Valley Ski Area, Inc.*, 718 F.2d 1075, 1083 (Fed. Cir. 1983)], this court specifically noted a distinction between cases in which only method claims are asserted to have been infringed and cases like the present case, where [patentee] alleged infringement of all its apparatus and method claims. . . . The claimed method is the use of the product. Having sold the product unmarked, [patentee] could hardly maintain entitlement to damages for it use by a purchaser uninformed that such use would violate [patentee's] method patent.

822 F.2d at 1066. AMS argues that this case is inapposite, since a method of *using* a product (claimed in *Devices for Medicine*) is different than a method of making a product (which Klatt claims). Nevertheless, while the facts of the cases (making versus using) are different, the rationale behind the

(continued...)

with the spirit of the patent marking statute, requiring the patentee to put the world on notice of his patent if he is to collect damages.[12] It makes good sense to require patentees to mark their products even if the patent also alleges method claims; a patentee should not be relieved of its duty to alert the public that its product is patented simply because the patent also alleges method claims. Consequently, the court concludes that if AMS is to collect damages, it must have marked the Hydroflex, notwithstanding that the Klatt patent also contains method claims.

"The person under the duty to mark must so mark *all* patented articles made and sold. Thus omission from any substantial number constitutes noncompliance." 5 D. Chisum, *Patents*, sec. 20.03[7][c][iii] at p.20-258 (emphasis in original). AMS did not begin marking Hydroflex

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[11] (...continued)
marking statute remains the same: to the extent there is a tangible item to mark, a party is under an obligation to warn the world of his patent. He is relieved of this duty only when there is nothing to mark.

[12] "The Patent Act imposes a duty to mark on patent owners. The purpose of the statutory duty is to prevent patent owners from deceiving the public by distributing unmarked (and hence apparently copyable) articles which are in fact covered by a patent. . . . There is no duty to mark . . . patented processes. . . . The only consequence of failure to mark is a limitation on recoverable damages for patent infringement. If the patent owner . . . fails to mark as required, the patent owner may only recover damages for acts occurring after the infringer received notice charging infringement. The filing of suit for infringement constitutes notice." 5 D. Chisum, *Patents*, sec. 20.03[7][c] at p.20-249.

with the Klatt patent number until approximately three and one half months after the patent issued. (Tr. 521). As a result, MEC claims AMS cannot recover any damages before the filing of the complaint unless MEC received notice that it was infringing. AMS on the other hand claims 35 USC 287 "does not require marking or notice within any specific period after issue as a condition for recovery of damages for infringement, and the statute must be interpreted to provide some reasonable leeway or grace period to effect a label change and patent marking."

The court concludes that AMS is obliged to have marked all Hydroflexes subsequent to issue of the patent, except that it is allowed a relatively small number to be shipped unmarked as it readies the marking process. 5 D. Chisum, *Patents*, sec. 20.03[7][c][iii] n. 109[13] and 20.03[7][c][iv] & n.133. AMS did not even begin the internal process for marking Hydroflex until two months after the patent issued on July 1, 1986, and it did not begin shipping marked Hydroflexes until October 15, 1986, three and one half months after the Klatt patent issued. (Tr. 521). By the court's calculation, during that three and a half month time span 1,939 Hydroflex units were shipped without the patent marking. (Ex. 109). Further analysis of this same record of shipments discloses

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[13] Chisum makes note of *Hazeltine Corp. v. Radio Corp. of America*, 20 F. Supp. 668 (S.D.N.Y. 1937) which states: "It is . . . explicit that there must be marking of every patented article sold—subject, of course, to the implied exception of de minimus, as, for example, failure by mistake to mark a few articles in hundreds of thousands made and sold might not, I venture, be ground for refusing an accounting."

that during the period July 1, 1986 through December 31, 1986 the 1,939 unmarked units shipped exceed the 1,381 marked units shipped by 558 units. Moreover, if the 4,287 units shipped between January and the end of October 1987 are combined with the 3,320 units shipped in 1986, the percentage of unmarked units still exceeds 25 percent—hardly insignificant. AMS could have easily complied with the marking requirement simultaneous with the issuance of the Klatt patent by affixing an appropriate label on the outer packaging of Hydroflex units in its inventory. The court concludes that AMS plainly did not comply with the patent marking statute.[14]

35 USC 287 provides that "in the event of failure to so mark" as specified, no damages may be recovered against an infringer "except on proof that the infringer was notified of the infringement and continued to infringe thereafter." 5 D. Chisum, *Patents*, sec. 20.03[7][c][iv]. "In applying the notice provision, the cases generally require that the patent owner give specific and actual notice to the accused infringer charging infringement of the patent in question. It is not normally sufficient that the infringer has actual knowledge of the patent." *Id.*; *see also Devices for Medicine v. Boehl*, 822 F.2d 1062, 1066-67 (Fed. Cir. 1987) ("Absent notice, [infringer's] 'knowledge of the

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[14] "It is not the number of articles seen by the defendant which is controlling on an issue of marking . . . but whether the patentee performed his statutory duty which was a prerequisite to his in rem notice to the world, and hence, failing personal notice to the infringing defendant, a condition precedent to his cause of action for damages or accounting for profits." *Hazeltine Corp. v. Radio Corp. of America*, 20 F. Supp. 668 (S.D.N.Y. 1937).

patents' is irrelevant. Section 287 requires 'proof that the infringer was *notified of the infringement*' (emphasis ours).").

In the present case, it appears that MEC was aware of the Klatt patent soon after it issued. Thad Kryshak, MEC's local patent counsel, testified he learned of it from the Official Gazette some weeks after it issued. (Tr. 1371). Stuart Krieger testified that he was already aware of Klatt when James Elacqua called him about it a month after it issued. (Tr. 1766-68). Nevertheless, it also appears that MEC was not specifically notified of infringement until some two and one-half months later. Although Elacqua called Kryshak, Elacqua never accused MEC of infringement. (Tr. 1369-70; 1637). Similarly, Elacqua never told Krieger that AMS was accusing MEC of infringement. (Tr. 1762, 1767).

AMS would like the court to conclude MEC had notice because MEC was aware of the Klatt patent. But awareness is insufficient; AMS is only entitled to damages commencing from the time it specifically accused MEC of infringement. This it did not do until October 28, 1987, at which time the complaint was filed (but not served) and MEC was notified of the filing. (Tr. 1659-60). Clearly, AMS felt it advantageous to withhold making an explicit accusation of infringement to prevent a declaratory judgment suit from being filed by MEC; it bought AMS valuable time to attempt to settle the case without resorting to litigation. (Tr. 1106, 2408). This was a calculated risk; the parties still ended up in litigation, and as a result AMS' damages are significantly reduced as a consequence of its failure to give notice of infringement.

Thus, AMS' damages for lost profits are limited to November and December 1987 and appropriately determined as follows:

MEC's Total Unit Sales, all filled Flexi-Flates (Ex. 109).

	Domestic	International
November 1987	210	3
December 1987	181	22
Total	391	25

AMS 1987 Incremental Profit—Hydroflex Unit (Ex. 100).

Domestic Sales	$2,266.00
International Sales	832.00
391 x $2,266.00 =	$886,006.00
25 x 832.00 =	20,800.00
AMS Total Lost Profits	$906,806.00

C. Reasonable Royalty

The court next considers two related issues concerning reasonable royalty. First, AMS contends that it is entitled to a reasonable royalty commencing January 1988. From that time forward, MEC was principally selling the vacuum pack Flexi-Flate, but was also selling out its remaining stock of the wet pack Flexi-Flate; AMS claims it is entitled to a royalty of 25 percent of the net sales price for each of the wet packs sold. Second, in order that the record be complete, the court will also discuss what its findings on reasonable royalty would have been had it not found that AMS was entitled to lost profits.

The legal authority relevant to the two issues is the same. If a court finds that damages should not be measured by lost profits, then it must find that the patent owner is entitled to a reasonable royalty under 35 USC 284. *Panduit*, 575 F.2d at 1157. A reasonable royalty is "the floor below which damages shall not fall." *Stickle v. Heublein, Inc.*, 716 F.2d 1550, 1561 (Fed. Cir. 1983). An award based on a reasonable royalty after infringement "must be at least a close approximation of what would be 'adequate to compensate' for the 'use made of the invention by the infringer.' " *Fromson v. Western Litho Plate and Supply Co.*, 853 F.2d 1568, 1575 (Fed. Cir. 1988). The fictional negotiation is as of a date when infringement by the defendant began and is based on the assumption that the patent was valid. 5 D. Chisum, *Patents*, sec. 20.03[3][a].

The reasonable royalty analysis creates a hypothetical licensing negotiation between a willing licensor and a willing licensee and determines the reasonable royalty for the parties. *Stickle*, 716 F.2d at 1561. In determining the result of such a hypothetical negotiation, the court may consider: 1) prior existing licenses, if any, under the patent; 2) industry custom and licenses on comparable patents; 3) the patent owner's licensing policy and the relation between the parties; 4) the infringer's anticipated profits; 5) comparative utility and noninfringing alternatives; 6) collateral benefits and convoyed sales; 7) improvements, small parts and apportionment; 8) state of development and commercial success; and 9) duration of patent. 5 D. Chisum, *Patents*, sec. 20.03[3][b]; *see also Panduit Corp. v. Stahlin Bros. Fibre Works*, 575 F.2d 1152 (6th Cir. 1978); *Georgia-Pacific Corp. v. United*

States Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), *modified and aff'd*, 446 F.2d 295 (2d Cir. 1971).

In addition, the court may utilize expert testimony to aid its determination. *Trell v. Marlee Electronics Corp.*, 912 F.2d 1443, 1446 (Fed. Cir. 1990). Similarly, the court is permitted, and often required, to consider events and facts that occurred after the infringement, and could not have been known to or predicted by the hypothesized negotiators. *Fromson v. Western Litho Plate and Supply Co.*, 853 F.2d 1568, 1575 (Fed. Cir. 1988). The court is not limited to selecting one or the other of the specific royalty figures urged by counsel as reasonable. *Smith-Kline Diagnostics, Inc. v. Helena Laboratories Corp.*, 926 F.2d 1161, 1167-68 (Fed. Cir. 1991). The determination of a reasonable royalty must be based upon the entirety of the evidence and the court is free to, and indeed must, reject royalty figures proffered by the litigants where the record as a whole leads the court to a different figure. *Id.*

The court will first examine what a reasonable royalty would be in this case. The court takes the following into consideration in arriving at a reasonable royalty:

First, there is no established royalty rate for the Klatt patent. There were, however, royalties negotiated between the parties with respect to other aspects of penile prosthesis products. While these licenses are not on Klatt but on interferences, and thus accorded lesser weight by the court, they are indicative of the "ballpark" for licenses on penile prostheses, and therefore relevant. (Exs. 122, 123, 124A).

Second, AMS had little incentive to license the Klatt patent. AMS was using the patent, and had the manufacturing capacity to meet demand for prefilled self-contained protheses. By granting MEC a license, AMS would have been assisting the competition in a highly competitive market, and in a submarket where it clearly was gaining an edge.

Third, MEC had an immediate need to get a prefilled and sterile self-contained prosthesis into the market. In the court's opinion, however, this does not mean that MEC would have paid any price AMS sought for a license under Klatt. Certainly, Klatt was available and this was an incentive to MEC, since getting into the market was important. However, in an arms length transaction, MEC would not have paid more for Klatt than it was worth in increased profits to the company; no reasonable business person would. If the price of the license was too high, MEC would have attempted to design around Klatt by continuing to develop a vacuum package.

Fourth, the opinion of others knowledgeable about royalties in the industry are relevant. Dr. Latham, AMS' economist, testified that an appropriate royalty would be around 35 percent of the selling price. (Tr. 837-39). The court is inclined to give somewhat lesser weight to Dr. Latham's estimate of a reasonable royalty because he has no experience actually negotiating them. MEC called Lawrence Swaton, a health care industry consultant who has negotiated licenses. He said he would pay a royalty of less than one percent for the Klatt patent. (Tr. 2050). He also said the highest royalty he ever personally encountered was eight percent. (Tr. 2053).

Determining a reasonable royalty from a hypothetical negotiation is not easy; the process is truly artificial.[15] Obviously, since the court must arrive at a figure, it cannot determine that negotiations broke off—that the seller refused to go lower and the buyer refused to go higher. Basically, the court must pretend these parties are locked in room and forced to remain there until they arrive at a figure. Given the evidence, it is reasonable to conclude that if locked in a room, the parties would have arrived at a figure somewhere between those suggested by Dr. Latham and Mr. Swaton.

In the court's view, the one percent royalty posited by Mr. Swaton does not sufficiently take into account MEC's immediate need to get the prefilled prosthesis into the marketplace. MEC would have been willing to pay more than one percent because it would be cheaper than de-

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[15] In an especially thoughtful opinion several years ago, Chief Judge Markey observed that determining a fair and reasonable royalty often involves "more the talents of a conjurer than a judge." *Fromson*, 853 F.2d at 1574. He observed, and this court agrees, that creating hypothetical negotiations is an imperfect method for determining a reasonable royalty. It "requires a court to imagine what warring parties would have agreed to as willing negotiators." *Id.* at 1575.

Similarly, using this method risks creating the perception that infringing patents is a no-risk proposition, with the sole penalty consisting of forcing the infringer to pay the royalty it would have paid in the first place. The court agrees with Chief Judge Markey that the proper method of recognizing that an infringer is not like a willing licensee is to consider increased damages under section 284 for willfulness or for attorney's fees under section 285, rather than artificially inflating the royalty rate, as AMS seems to suggest. *Id.* at 1576.

veloping an alternative packaging technology. And more importantly, paying the royalty would get MEC into the market more quickly. By the same token, the 35 percent royalty opined by Dr. Latham does not take sufficient account of MEC's need to make a profit. Also, the court finds that while Dr. Latham is a good economist and credible witness, his opinion on this subject is entitled to lesser weight because he has no experience actually negotiating licenses. The court is of the opinion that MEC would have refused to pay a royalty of 35 percent, but would have been willing to pay something lower.

After closely examining all the evidence submitted by the parties, the court concludes that the hypothetical negotiation would have resulted in a license of the Klatt patent for 8 percent of the net selling price of the wet pack Flexi-Flate.

The court next examines AMS' claim for post-January 1, 1988 damages. AMS claims it is entitled to a 25 percent royalty for wet packs sold after January 1, 1988 because this is a "conservative" estimate of the amount MEC saved by not having to repackage the remaining wet packs in vacuum packaging. As justification for its royalty number, AMS points to MEC's policy of allowing buyers to return inadvertently opened wet packs and receive a 65 percent credit. (Ex. 37 at 5; Tr. 839-41). Apparently, the inference AMS wishes the court to draw is that the returned prostheses were repackaged and resold. According to AMS, since MEC was willing to credit its customers for 65 percent of the purchase price for inadvertently opened packages, 35 percent must represent the value of the packaging. As a result, says AMS, the amount MEC saved by not repacking wet packs was 35

percent. AMS claims a 25 percent royalty, as opposed to 35 percent, "to allow for some conservatism in the estimate of total damages." (Tr. 841).

The court is disinclined to follow the tenuous logic of this argument. First, without more, the court cannot say that 35 percent represents MEC's packaging value. Certainly there was little, if any, evidence to support this contention. The return program may simply have been a marketing tool bearing no relation to the cost of packaging or repackaging. Similarly, and more importantly, a reasonable royalty should not be gauged by an estimate of the infringer's savings, but by what would be negotiated in a hypothetical arm's length transaction between the parties. Consequently, the court finds and concludes that to the extent AMS is entitled to a reasonable royalty, whether post-January 1988 or in lieu of lost profits, the figure must bear a reasonable relationship to what the parties would have negotiated, in this case 8 percent of the net sales price.

For purposes of assessing damages the post January 1, 1988 royalty amounts to $46,264.24 (Total 1988 net wet pack Flexi-Flate sales of $578,303 x .08 = $46,264.24).

D. Willfulness

The court next turns to AMS' contention that it is entitled to triple damages because MEC willfully infringed its patent. To establish willful infringement, a plaintiff must prove by clear and convincing evidence that the defendant acted with no reasonable basis for believing it had the right to do so. *State Industries Inc. v. Mor-Flo*

Industries, Inc., 883 F.2d 1573, 1581 (Fed. Cir. 1989). The Court of Appeals for the Federal Circuit has emphasized that district courts are not to look to any one factor as dispositive, but instead are to look to the "totality of the circumstances." *E.g., State Industries*, 883 F.2d at 1581 *citing E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1440 (Fed. Cir. 1988); *Studiengesellschaft Kohle mbH v. Dart Industries*, 862 F.2d 1564, 1573 (Fed. Cir. 1988). Among the factors the court should consider are: 1) whether the infringer, when he knew of the other's patent protection, investigated the scope of the patent and formed a good faith belief that it was invalid or not infringed; 2) whether the infringer deliberately copied the ideas or design of another; and 3) the infringer's behavior as a party to the litigation. *Bott v. Four Star Corp.*, 807 F.2d 1567, 1572 (Fed. Cir. 1986).

1. Krieger Opinion

Stuart Krieger testified in person and by deposition during the trial. Mr. Krieger remains a senior patent attorney at Bristol Meyers' headquarters in New York City. MEC is a subsidiary of Bristol Meyers, and Krieger was in charge of MEC's patent matters. When the Klatt patent issued on July 1, 1986, he had been a patent attorney for about ten years. (Tr. 592).

In late July 1986, Krieger learned of Klatt through his own efforts. (Ex. 118). He became aware of it because he had a patent office subscription for the class of patents in which Klatt appeared. (Tr. 596; 1059). Upon discovering it, he immediately contacted Garry Carter, MEC vice president for scientific affairs. (Ex. 118; Tr.

1203). He then contacted Thad Kryshak, who had prosecuted the Goldberg patent, because he presumably knew something about the art. (*Id.*; Tr. 1071). During the rest of the month of July and into late August, Krieger authorized a number of patent validity searches, including searches in the United States (by Sherman & Shalloway), Japan (by Aoki & Associates), and Britain (by Mathes & Squire), (Ex. 118; Tr. 1071-72), and several in West Germany. (Tr. 602-03, 609, 611). He also ordered an in house computer validity search done on the Klatt patent.[16] (Tr. 613). Similarly, by the end of August, Krieger reviewed the Klatt prosecution history and file wrapper. He testified he understood the nature of the prior art, as well as the arguments of prosecuting counsel and positions taken by the examiner in connection with the prosecution. (Tr. 625-26).

Krieger says he took into consideration his study of the Klatt prosecution, a physical Hydroflex sample, the search results, and conversations with MEC research and development people. (Tr. 634-39). He alleges, however, that he is unable to recall any details of the searches that were performed after he became aware of the Klatt patent. (Tr. 605-06, 609-10, 613-14). He could not remember what references he relied upon in reaching his opinion. (Tr. 640-44). He could not recall even the most general details of technical teachings in the references that he found most pertinent, nor how the relied upon references fit together to invalidate Klatt. (Tr. 643-44).

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[16] Unfortunately, the results of the searches are not part of the record, since MEC asserts the attorney-client/work product privileges as to such matters.

He could not identify any of the logic he relied upon in forming his opinion other than: "If you combine the teachings of this reference with those of another reference, it renders the Klatt patent and all its claims invalid." (Tr. 642). However, Mr. Krieger did remember that, based on his study, he concluded that Klatt was invalid for obviousness. (Tr. 639).

At the end of August or the beginning of September 1986, Krieger informed Robert Helbling, the president of MEC, of his opinion that the Klatt patent was invalid for obviousness. (Tr. 645, 647, 1763). The opinion was rendered orally, either in person or over the phone. (Tr. 644, 647). Krieger states that it was his normal practice to provide opinions to Helbling orally, and in layman's terms, because Helbling has no understanding of patent law. (Tr. 648; 1761). According to Helbling, Krieger told him that the wet pack Flexi-Flate fell literally with the scope of the Klatt claims, and discussed intraocular lenses and mammary protheses with him. (Tr. 1151, 1153). However, Helbling basically relied on his patent counsel's bottom line assessment, and was uninterested in the rationale used to reach the conclusion: "[Krieger] doesn't usually go into a lot of detail on his opinions with me any more than my finance individual would go into detail with me on how he decides to calculate depreciation." (Tr. 1154).

In order for the court to be able to find that the defendant undertook a good faith effort to determine the validity of the patent, the court must be able to ascertain that defendant undertook the necessary analysis. Standing alone the fact that Mr. Krieger rendered his opinion orally is of little consequence. A well-supported oral

opinion can be just as indicative of good faith as a written one. The advantage of a written opinion, however, is that the court can more easily examine the thought process by which the conclusion was derived. With an oral opinion, the court is left to draw inferences from the testimony and source documents of record.

Robert Helbling indicated that the opinion he received was "conclusory," did not indicate a search for prior art had been made, identified no prior art, did not indicate how the art relied upon was more pertinent that the art considered by the PTO, and did not discuss any of the secondary considerations of patentability. (Tr. 1153-59). He stated that he was uninterested in any of the premises used to arrive at the conclusion the patent was invalid. As a layman, this is perhaps not surprising. But even if Mr. Helbling delegated the determination of validity/invalidity to his attorney, the court still must determine whether the defendant had a good faith belief that the Klatt patent was invalid. MEC may not employ a "clean heart, empty head" philosophy by divorcing itself from the advice of its counsel. Thus, the court must examine, as part of the totality of the circumstances, whether the defendant's attorney had a good faith belief in the invalidity of the Klatt patent.

The court has endeavored to ascertain how Mr. Krieger arrived at his conclusion, but without much success. Mr. Krieger's inability to recall, selectively it seemed, many of the salient details surrounding his rendering of the oral opinion of invalidity is indeed troubling. After hearing his in-court testimony and portions of his deposition read, and observing his demeanor, the court is left with the firm impression that Mr. Krieger

knew more than he was telling, and that what he knew was against the interests of MEC.

In addition, the court was unable to examine much of the relevant documentary evidence, owing to MEC's assertion of the attorney client privilege to numerous documents relevant to the issue of willfulness. Thus, the court was without the benefit of what thought went into Mr. Krieger's opinion, and whether Mr. Krieger found pertinent patents or documents not considered by the examiner. The court concludes that these documents were not released because they indicate a lack of support for invalidity. *Cf. Fromson v. Western Litho Plate & Supply Co.*, 853 F.2d 1568, 1572-73 (Fed. Cir. 1988) ("Where the infringer fails to introduce an exculpatory opinion of counsel at trial, a court must be free to infer that either no opinion was obtained or, if an opinion were obtained, it was contrary to the infringer's desire to initiate or continue use of the patentee's invention.")

The record does not disclose that Mr. Krieger found art more pertinent than that cited to the examiner. Nor is there any indication that he considered the secondary considerations. What the record does reflect is a massive failure of memory on the part of Mr. Krieger. As a consequence the court is left to conclude that Mr. Krieger's opinion of invalidity lacked sufficient support to constitute an authoritative opinion upon which good faith reliance on invalidity may be founded. *Bott v. Four Star Corp.*, 807 F.2d 1567, 1572 (Fed. Cir. 1986).

2. Smith Opinion

In early November 1987, Krieger requested that outside counsel render an opinion on the validity of Klatt.

(Ex. 118; Tr. 650, 1751). His request came after AMS had filed (but not served) the original complaint in this action. He stated he was not aware of the commencement of litigation until February 1988 when Pfizer (AMS' parent) provided Bristol Meyers with a courtesy copy of the complaint. (Tr. 1764).

Krieger called Jamie Smith of Allegretti & Witcoff to undertake the evaluation. (Tr. 1706). She conducted what in the court's opinion was a thorough evaluation of the validity of the patent. (Tr. 1707-60).[17] She concluded that the claims of the patent would be ruled invalid as obvious over prior art, and that in her opinion Dr. Austad's work with tissue expanders was so close that a "very decent argument" for anticipation could be made with respect to some of the broad claims. (Tr. 1741). She informed Krieger of this conclusion over the telephone in December 1987 or January 1988. (Tr. 1740). She said "he was very relieved and he said that was the opinion that he had reached and the opinion he had give orally some time ago." (Tr. 1741). Krieger asked her to reduce her opinion to writing, which was completed as of February 24, 1988. (Ex. 711; Tr. 1741-42).

In the court's view Ms. Smith's opinion arrived too late to be reasonably relied upon by MEC. It was not rendered until MEC had been infringing the Klatt patent for almost twenty months. The opinion was written after MEC had stopped making the wet pack, and after suit

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[17] During her testimony, she also stated that Krieger turned up the intraocular lens references which she relied upon and which proved to be a cornerstone of MEC's obviousness defense. (Tr. 1721-22, 1741).

had been filed in the case. In addition, the opinion relies on art which is the same as or no more pertinent than that considered by the PTO. Moreover, Mr. Helbling had no knowledge of the Smith opinion in 1986-87 and testified that he relied only on Mr. Krieger's opinion. (Tr. 1165-66).

3. Copying

Finally, the court finds relevant to the willfulness calculus the actions of Mr. Goldberg. The record amply demonstrates that MEC was working, albeit without much success, on a pouch and tube configuration prior to Goldberg seeing AMS' product at the 1985 AUA convention. There can be little question that seeing AMS' product at the convention, and later in hand, provided much of the impetus for what turned out to be the final Flexi-Flate wet pack product. Accordingly, the court finds MEC copied, to a large extent, AMS' Hydroflex packaging design.

After carefully scrutinizing the evidence, under the totality of the circumstances, the court finds by clear and convincing evidence that MEC willfully infringed the Klatt patent.

4. Amount of Increase

The patent remedy statute, 35 USC 284, authorizes the court to "increase the damages *up to* three times the amount found or assessed." (court's emphasis). If the infringer's conduct warrants an exemplary award, the amount should be tempered by the goals of deterring and

punishing the willful infringer on the one hand, and of fully compensating but not unjustly enriching the patent owner on the other. 5 D. Chisum, *Patents*, 20.03[4][b] at 20.174.3, 20-177.

The court finds that the goals of deterrence and avoidance of unjust enrichment are met by enhancing plaintiff's compensatory award by a multiplier of 1.5.

5. Attorney Fees

35 USC 285 authorizes the court "in exceptional cases" to award "reasonable attorney fees" to the prevailing party. The award of such fees is discretionary with the trial court, but such discretion may only be exercised upon a specific finding of exceptional circumstances. 5 D. Chisum, *Patents*, sec. 20.03[4][c]. Often, when a court makes a finding of willful infringement, it will also find that the case is exceptional and award attorney fees.

In the present case, however, the court finds that the better exercise of discretion is to deny attorney fees despite the finding of willfulness. In the court's opinion, whether plaintiff's evidence of willfulness reached the threshold of "clear and convincing" was a close call. Ultimately, the court decided it did, but considerable thought had to be given to that finding before it was made. Basically, there was a lack of evidence of good faith rather than explicit evidence of bad faith. Stuart Krieger was unable to recall the basis for his oral opinion. Robert Helbling was uninterested in anything but the bottom-line opinion. There was no available documentary evidence to establish good faith.

In addition, this was a hard fought case in which neither side gave an inch. Both parties spent a great deal of money prosecuting and defending the case. MEC spent over a million dollars on attorney fees, and there is no reason to believe AMS spent anything less, although AMS' chairman Robert Buuck, had no first hand knowledge as to how much AMS or its parent had expended in legal fees. (Tr. 2389).[18] To be sure, Mr. Buuck is no stranger to the high costs associated with litigation, a fact further evidenced by his conversations with the president of MEC in 1985 in reference to another patent dispute wherein he stated that the parties should settle their differences ". . . so that we would not have to be

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[18] The court had the following colloquy with Mr. Buuck:

> THE COURT: There has been testimony that has come out during the course of this trial MEC has expended more than a million dollars in fees to defend this case. My question to you, sir, are you in a position to disclose to the Court the amount of money that AMS has paid for outside legal counsel to prosecute this case?
>
> THE WITNESS: No, sir, I don't have that information. I would disclose it if I had it. I do not have that information. Part of that is because of the process by which we budget—or reimburse legal fees through our parent company, Pfizer. I don't have access to all that.
>
> THE COURT: And it is of no personal concern to you as chairman?
>
> THE WITNESS: Oh, yes, it is a concern, sir. I mean, I can't tell you how much it troubles me that these kinds of expenses and proceedings go on. It is a great concern. But I don't know the specific number.

(Tr. 2389-90).

involved in legal court battles where only the attorneys win" (Tr. 1178)—truly a self-fulfilled prophecy when applied to this case.

AMS played hardball just like MEC did; for one party to say the other "started it" would be like the pot calling the kettle black. Some examples–

> James Elacqua of AMS called MEC's patent attorneys and brought Klatt to their attention, but stopped short of alleging infringement. AMS later attempted to make this telephone call into something more, an "implicit" allegation of infringement, when the need arose due to the patent marking problem. (Tr. 1103, 1767).
>
> AMS filed the original complaint in this matter in October 1987, but did not serve it, until December 1987. An amended complaint was served in February 1988.
>
> AMS refused to admit that MEC's vacuum pack did not infringe the Klatt patent until it was ordered to do so by the court.
>
> Lead counsel for both parties kept the court busy with numerous discovery disputes—the type best reserved for the sandbox spats of children rather than advocacy in a federal court.
>
> Tensions during this trial were higher than is usual. Remarks made during the trial were more like brickbats thrown at opposing counsel than advocacy.
>
> The parties are familiar litigation opponents, having litigated cases in the past. Likewise, they

> appear to be litigation opponents for the foreseeable future.[19]

Given the closeness of the willfulness issue, the conduct of the parties, and the totality of the circumstances, the court finds that consistent with the American rule the better exercise of discretion requires that each party bear its own attorney fees.

IX. MEC Counterclaims

MEC has asserted counterclaims. The first counterclaim is for declaratory judgment of invalidity and non-infringement. In light of the court's earlier finding upholding the validity of the Klatt patent, there is no need to address this issue further.

The second counterclaim is for an alleged breach of warranty. A warranty is an assurance by one party to a contract of the existence of a fact upon which the other party may rely. It is intended to relieve the promisee of any duty to ascertain the fact for himself, and amounts to a promise to indemnify the promisee for any loss if the fact warranted proves untrue. *Dittman v. Nagel*, 43 Wis. 2d 155, 160, 168 N.W.2d 190, 193 (1969).[20]

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[19] MEC has filed an action against AMS in the United States District Court for the District of Minnesota, Case No. 3-91-CV-348 alleging infringement of three MEC patents by AMS' making and selling of its revised self-contained inflatable penile prothesis. (Ex. 181).

[20] The parties agree Wisconsin law controls on the counterclaims.

MEC claims AMS breached warranties contained in agreements the parties negotiated to resolve two interferences and an arbitration. One of the agreements contained language to the effect that the parties "warranted that there are no other issued patents, nor any pending applications for letters patent . . . with respect to any device disclosed to the warranting party by the other party which would result in any infringement or other potential litigation issue." MEC states the Klatt patent application was pending during the negotiation and execution of the agreements, and that AMS' failure to disclose Klatt breached the agreements' warranties.

There are several considerations which enter into whether there was a warranty which covered the disclosure of Klatt or not. First, the court must consider whether the contract is ambiguous. Words or phrases in a contract are ambiguous when they are susceptible of more than one meaning. *Patti v. Western Machine Co.*, 72 Wis. 2d 348, 351-52, 241 N.W.2d 158, 160 (1976). Absent ambiguity within the document, the construction of a contract presents a question of law. *Lakeshore Commercial Finance Corp. v. Drobac*, 107 Wis. 2d 445, 457, 319 N.W.2d 839, 842 (1982). An agreement should be given a reasonable meaning so that no part of the contract is surplusage. *Koenings v. Joseph Schlitz Brewing Co.*, 126 Wis. 2d 349, 366, 377 N.W.2d 593, 602 (1985) (provisions of a contract read together).

MEC concentrates on the language in paragraph 17.8 of the Hakky agreement (Ex. 122), and to a lesser extent, on paragraph 19.8 of the Finney agreement (Ex. 123). The preceding paragraphs are also relevant, if the court is to heed the caveat that it is to give a reasonable mean-

ing so that no part of the contract is surplusage. For clarity's sake, the court will simply recite them. First, paragraphs 17.7 and 17.8 of the Hakky Agreement, which read as follows:

> 17.7 AMS and MEC each represent that their respective current technical disclosures to each other are accurate and complete *with respect to the patent issues in the '779 interference.*
>
> 17.8 AMS and MEC each warrant that there are no other issued patents, nor any pending applications for letters patent, reissue, continuation, continuation-in-part, or divisions *with respect to any device disclosed to the warranting party by the other party which would result in any infringement or other potential litigation issue.*

(Ex. 122 at 24) (emphasis supplied). Also relevant are paragraphs 19.7 and 19.8 of the Finney Agreement, which read:

> 19.7 AMS and MEC each represent that their respective current technical disclosures to each other are accurate and complete *with respect to the patent issues in the '149 Interference.*
>
> 19.8 AMS and MEC each warrant that there are no other issue patents, nor any pending applications for letters patent, reissue, continuation, continuation-in-part, or divisions *with respect to the subject matter of the '149 Interference which would result in any infringement or other potential litigation issue.*

(Ex. 123) (emphasis supplied).[21]

Giving the terms their ordinary meaning, and reading paragraphs 17.8 and 19.8 with their corresponding preceding paragraphs, the court does not find the warranty ambiguous. Paragraph 17.7 requires the "current technical disclosures" to be "accurate and complete with respect to the patent issues in the '779 interference." This is not ambiguous. In light of paragraph 17.7, paragraph 17.8 is not ambiguous either. It is clear to the court that what is meant by "with respect to any device disclosed to the warranting party by the other party" in paragraph 17.8 relates back to the "current technical disclosures" of paragraph 17.7. And the current technical disclosures only had to be "accurate and complete with respect to the patent issues in the '779 interference." In other words, the "warranty" in 17.8 requires the parties to disclose only those patents implicated by the limited "current technical disclosures" referred to paragraph 17.7. The Klatt patent was not required to be disclosed

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[21] The "'360" Binding Arbitration Agreement contains similar language in paragraphs 23.8 and 23.9. *See* Ex. 124A. However, the "'360" Settlement Agreement (Ex. 124B) states:

> This Agreement specifically supersedes the BINDING ARBITRATION AGREEMENT . . . between the parties and all prior and contemporaneous discussions, understandings or verbal agreements between the parties as they affect the resolution of the present dispute. . . . Neither party shall be bound by any . . . warranty . . . with respect to the resolution of the present dispute other than expressly stated in this Agreement, or as subsequently set forth in writing and executed by a duly authorized officer of the party to be bound by it.

because it does not relate to the interferences.[22] (Tr. 1414-15).

Even if the court were to find that the warranty was ambiguous, the court would reach the same result based on the intent of the parties. Assuming arguendo that the contract was ambiguous, MEC would be entitled to offer extrinsic evidence of the parties' intentions at the time the agreements were executed. *Wisconsin Real Estate Investment Trust v. Weinstein*, 509 F. Supp. 1289, 1295 (E.D. Wis. 1981); *Capital Investment v. Whitehall Packing Co.*, 91 Wis. 2d 178, 280 N.W.2d 254 (1979). However, any ambiguities must be construed in a manner consistent with the agreement's purpose and conducive to the accomplishment of that purpose. *Capital Investment*, 91 Wis. 2d at 189, 191.

The court makes the following findings of fact with respect to the negotiations. AMS and MEC had been developing their respective Hydroflex and Flexi-Flate devices concurrently. AMS had filed and obtained two patents covering different aspects of a particular self-contained inflatable device. MEC, in turn, was a licensee under two patent applications filed by Dr. Said Hakky and Dr. Roy Finney.

In 1982 and 1983, the PTO declared interferences between the AMS patents and the Finney and Hakky patent applications. (Ex. 133- 35; Tr. 1390-91). As often happens, two or more persons may invent substantially the same subject matter at approximately the same time, and file patent applications claiming that subject matter.

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[22] The same analysis applies to paragraph 19.8.

When that occurs, the PTO must determine who made the invention first, and the first inventor is then entitled to a patent containing claims directed to that invention. The inventions which are the subject matter of the interferences are defined as "counts", and the PTO must determine, for example, who first conceived the invention of the "count," who first reduced it to practice, and what if any, diligence existed. (Tr. 1396-97). Each interference at issue between AMS and MEC had as its subject matter something that was defined and the parties knew what it was. (Tr. 1397). Neither interference involved the subject matter of the Klatt patent in any way. (Tr. 1414-15).

In early 1984, representatives from AMS and MEC met briefly in Puerto Rico. They agreed to discuss the possibility of settling the interferences between the parties. (Tr. 1391). At this time, and throughout the subsequent negotiations, the two companies were direct competitors, and each jealously guarded its proprietary technology. (Tr. 2264-65). However, the fact of the interferences and the desire to settle them required that certain limited technical exchanges be made. (Tr. 2266-67).

On June 14, 1984 the parties met again in the offices of MEC's counsel to discuss the ongoing interferences and whether it would be possible to resolve them short of having one party lose and risk not being able to practice the counts of the interference. (Tr. 1391-92, 1395-96).

On August 30, 1984, the parties met in Minneapolis.[23] (Tr. 1392). They signed a confidentiality agreement governing the exchange by AMS and MEC of "drawings . . . representative of the AMS Hydroflex device and MEC Flexi-Flate device." (Tr. 139-41). This confidentiality agreement was ultimately superseded by the final agreements. (Tr. 1403-04). In order to set the framework of settlement, each party made available to the other certain specific drawings and explained the hydraulic systems employed. (Ex. 143-45; Tr. 1288, 2269, 2396-98). Both parties' drawings showed the penile prosthesis device itself and neither specified whether the devices were prefilled. (Tr. 1398, 2398, 2405, 2412-14). Neither party disclosed to the other—at the August meeting or at any other meeting—a prefilled and sterile product; nor was there a discussion of how the two products would be packaged. (Tr. 1188-90, 1287, 1398-39, 1411-12, 1414-15, 2269-70, 2405). Similarly, no methods of packaging or sterilizing a packaged fluid-containing prosthesis were disclosed by either party at any time (even though both parties had such products generally in mind at the time and both were interested in seeking patent protection on them). (Tr. 1141-4). These matters (prefilling, presterilizing and methods of achieving it), were not exchanged because they were not within the interferences or the patents/applications under discussion. The discussions had limited objectives and, as direct competitors, neither party wanted to disclose unnecessary proprietary information to the other. (Tr. 2411). As of the critical

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[23] The court found Dr. Christopher Porter's deposition testimony especially helpful and credible with respect to the parties' conduct and intent. (Tr. 2393-2423).

August and December 1984 meetings neither side had a patent application on file regarding a prefilled prosthesis. Indeed, MEC's technical representatives testified that MEC's drawings were left vague on issues that were not squarely encompassed in the then pending interferences. (Tr. 1283-86; see also 2413). Even if it is accepted, as argued by MEC, that the drawings were disclosed to create a settlement broader than the interferences, each party necessarily took the risk of its own nondisclosure because the settlement agreements were specifically based on what was disclosed, not on what might have been disclosed in 20/20 hindsight. (Tr. 2418-23).

MEC asserts that at this meeting, it raised the issue of another patent by Dr. Finney (U.S. Patent No. 4,353,360) and the issue of whether or not the Hydroflex as shown in the drawing infringed it. (Tr. 1287-88; 1399). However, AMS was already aware of the '360 patent (Ex. 147, 138; Tr. 1400-02) and, long before the August meeting had already "scrapped out" its prior version of the Hydroflex in view of the '360 patent. (Tr. 484; 2409-11). Moreover, the '360 patent became an issue because AMS' technical disclosure implicated it. By contrast, nothing MEC chose to disclose to AMS ever implicated the Klatt patent in suit.

The parties convened again in December 1984 to continue their negotiations to settle the existing disputes. (Ex. 150-58; Tr. 1393-95, 1405). At some point during negotiations, MEC raised the existence of a reissue application. At the time of the settlement discussions, MEC was attempting to present claims by reissue that would be placed in interference with one or more of the patents that were already involved in one of the then pending in-

terferences between the parties. This reissue application thus was directly related to one of the interferences and was ultimately incorporated into the agreements. (Tr. 1405-06). All AMS received from MEC regarding the reissue was information available to the public. (Tr. 1406-07). Again, the reissue application arose from matters actually in controversy, something which did not occur regarding Klatt.

Thereafter, the parties continued to negotiate the agreements necessary to settle all the pending disputes. (Tr. 1393-94). Drafts of agreements were prepared, and those drafts were carefully studied and revised by all parties. (Ex. 150-58; Tr. 1403, 1409-11). The individuals involved on behalf of MEC in this matter included Dave Sanders (president of MEC), Garry Carter (chief technical officer of MEC), Robert Wiles (CEO of MEC), and four sets of patent and general attorneys. The attorneys consisted of Thad Kryshak of Quarles & Brady, and in-house patent counsel from Bristol Meyers and sister corporation Zimmer, Inc. (Tr. 1195). MEC was fully involved in the drafting of the terms of the settlement agreements. (Tr. 1403, 1411).

Ultimately, in March and April 1985 the parties executed three separate agreements settling, respectively, the Hakky-AMS interference (Ex. 122), the Finney-AMS interference (Ex. 123), and providing for arbitration of the '360 patent (Ex. 124A). The Hakky-AMS interference settlement also included Dr. Hakky as a party to the agreement. (Tr. 1394-95). Each agreement contained a specific integration clause which was understood by Mr. Wiles when he signed the agreements. (Tr. 1191-92, 1403). MEC knew full well that any alleged prior under-

standing or promise, whether written or oral, was extinguished by the final settlement agreements.

In general terms, the two interferences were settled by agreements that the PTO would decide who had priority of the inventions. However, the winning party would automatically licenses the losing party under any issued patent. Therefore, both parties were protected, no matter who won the interference.

With respect to the '360 patent, the parties agreed to arbitrate the question whether AMS' disclosed Hydroflex device fell with the scope of the '360 patent claims, by submitting the issue to a neutral third party. Again, the parties agreed that the winning party would license the patent to the losing party.

With respect to the above '360 patent Binding Arbitration Agreement, the parties began the process of arbitration, and chose an arbitrator. Thereafter, AMS and MEC agreed to resolve the matter outside of arbitration. To mollify Dr. Finney, who had a license agreement with MEC under the '360 patent, the two companies each paid Dr. Finney $ 50,000 in return for MEC granting AMS a nonexclusive, paid up license under the '360 patent to make, use and sell the Hydroflex device. (Ex. 124B).

The court concludes on these findings of fact that MEC's claim that the intent of the agreements was broader than the agreements executed by the parties ignores the circumstances of the negotiations and common business realities. AMS and MEC were direct competitors in the highly competitive penile prosthesis market. They were not likely to disclose to each other their trade secrets, confidential business information, future product

improvements or intentions without a clear motivation and a plainly worded agreement. There is no evidence of any agreement that the disclosures be any more broad than that which is explicitly stated. (Tr. 2406). These competent and represented business persons would not agree to "disclosures" without clearly and explicitly defining their parameters. Both sides clearly disclosed only as much as was necessary to settle the issues at hand.

Next, the court turns to the balance of MEC's counterclaims. MEC's third counterclaim alleges that the nondisclosure of Klatt is intentional misrepresentation; the fourth counterclaim alleges negligent misrepresentation; and the fifth counterclaim alleges fraudulent misrepresentation. Each of these causes of action shares three common elements: 1) that the representation must be of fact and made by the defendant; 2) the representation of fact must be untrue; and 3) plaintiff must believe such representation to be true and rely thereon to his damage. *Whipp v. Iverson*, 43 Wis. 2d 166, 170, 168 N.W.2d 201, 203 (1969).

MEC stated in paragraph 36 of its proposed conclusions of law that:

> A warranty can constitute a misrepresentation and therefore be the basis of an action for false representation. See 93 C.J.S., *Warranty*, section 42. Even though fraud and breach of warranty claims can be "virtually impossible to distinguish . . .," a plaintiff in Wisconsin is entitled to a separate judgment for each claim. *Eklund v. Koenig & Assocs., Inc.*, 153 Wis. 2d 374, 378 (Wis. Ct. App. 1989).

The court has no reason to discount this authority. Nevertheless, the court finds that there was no misrepresentation of fact. Simply because the warranty represents that "there are no patents pending" does not make AMS' failure to reveal Klatt a misrepresentation. As discussed above, Klatt was not within the scope of the interferences and consequently was not required to be revealed in order to comply with the warranty. AMS had no duty to disclose Klatt. *Whipp*, 43 Wis. 2d at 170, 168 N.W.2d at 203. Also, there is no evidence in the record to suggest that AMS represented that it had no plans to prefill its prosthesis. Indeed, there is no persuasive evidence to suggest that this was even a topic for discussion. (Tr. 2406).

MEC also claims AMS is equitably estopped from asserting infringement. The court rejects this assertion outright because there has been no express misrepresentation.

Finally, MEC claims that it has an implied license to use the Klatt patent for the period of time after Klatt issued and before MEC switched to the vacuum pack. MEC states that, under the settlement agreements, it has a license to make, use and sell penile prosthesis under another AMS patent, U.S. Patent Number 4,383,525. MEC says that, according to AMS, defendant would have been unable to package and sell devices manufactured under the claims of that AMS patent because such a sale would infringe the claims of the Klatt patent in suit, also assigned to plaintiff. Thus, MEC contends that

> an implied license arises where, as here, a party sells a product or licenses a patent (the '525

> patent) that cannot be used (according to AMS) as intended, unless a license is implied under another patent or patents (the Klatt patent) owned by the same party.

MEC's proposed conclusions of law, paragraph 43.

The court rejects MEC's argument that is would be unable to practice the '525 patent unless it has an implied license for Klatt. As MEC has demonstrated with its own vacuum pack, there were other methods of transporting a penile prosthesis to the operating room in a prefilled and sterile condition.

X. Summary

The court has found the Klatt patent not invalid for obviousness. The patent is valid and was infringed. The court rejects MEC's counterclaims in their entirety. AMS is entitled to lost profits for the period October 1987 to December 1987 in the amount of $906,806.00 AMS is entitled to a reasonable royalty for the period January 1988 to December 1988 in the amount of $46,264.24, resulting in total damages of $953,070.24. AMS is entitled to a willfulness multiplier of 1.5 on its compensatory damages, resulting in $1,429,605.30 in total damages.

AMS shall submit a proposed judgment and memorandum related to its request for prejudgment interest within 30 days of today's date. MEC shall submit any objections to the proposed judgment, as well as any response to AMS' request for prejudgment interest within 20 days after receipt of AMS' submissions.

Dated at Milwaukee, Wisconsin this 25th day of June, 1992.

No. 92-1538

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

AMERICAN MEDICAL SYSTEMS, INC.,

Plaintiff/Cross-Appellant,

v.

MEDICAL ENGINEERING CORPORATION,

Defendant-Appellant.

December 6, 1993

ORDER:

A combined petition for rehearing and suggestion for regearing in banc having been filed by the APPELLANT, and a response thereto having been invited by the court and filed by the CROSS-APPELLANT, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the suggestion for rehearing in banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the suggestion for rehearing in banc be, and the same hereby is, DECLINED.

The mandate of the court will issue on December 13, 1993.

Circuit Judge ARCHER did not participate in the vote.

(3)

Supreme Court, U.S.
FILED
APR - 7 1994
OFFICE OF THE CLERK

No. 93-1431

IN THE

Supreme Court of the United States

OCTOBER TERM, 1993

MEDICAL ENGINEERING CORPORATION,
Petitioner,

vs.

AMERICAN MEDICAL SYSTEMS, INC.,
Respondent.

On Petition For A Writ of Certiorari To The United States Court of Appeals For The Federal Circuit

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BRIEF IN OPPOSITION FOR RESPONDENT AMERICAN MEDICAL SYSTEMS, INC.

RUDOLF E. HUTZ
Counsel of Record
JAMES M. MULLIGAN, JR.
GEORGE PAZUNIAK
R. ERIC HUTZ
CONNOLLY, BOVE, LODGE & HUTZ
1220 Market Street
P.O. Box 2207
Wilmington, Delaware 19899
(302) 658-9141

Attorneys for Respondent American Medical Systems, Inc.

PRESS OF BYRON S. ADAMS, WASHINGTON, D.C. 1-800-347-8208

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COUNTERSTATEMENT OF THE QUESTION PRESENTED

The damages provisions of the Patent Law are subject to a limitation in 35 U.S.C. § 287(a) (1988), which provides:

> Patentees, and persons making or selling any patented article for or under them, may give notice to the public that the same is patented . . . by fixing thereon the word "patent" or the abbreviation "pat.", together with the number of the patent. . . . In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice. Filing of an action for infringement shall constitute such notice.

The question presented is as follows:

Whether the Federal Circuit was correct in interpreting 35 U.S.C. § 287(a) to preclude the recovery of damages for patent infringement only for the duration of the patentee's "failure so to mark" the patented article with the patent number, an interpretation entirely consistent with prior precedent, or whether—as contended by petitioner—a three and one-half month delay in marking allows an infringer to escape damages for infringement for the life of the patent, except for damages accruing after the infringer is actually notified of the infringement by the patentee.

RULE 29.1 STATEMENT

Respondent American Medical Systems, Inc. is a wholly-owned subsidiary of Pfizer Inc.

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COUNTERSTATEMENT OF THE CASE

American Medical Systems, Inc. (AMS) instituted this action in the United States District Court for the Eastern District of Wisconsin against petitioner Medical Engineering Corporation (MEC) for deliberate and willful infringement of United States Patent No. 4,597,765 (the '765 patent). App. 1. AMS's '765 patent claims apparatus and methods for packaging fluid-containing penile prostheses in a pre-filled, sterile state. App. 5.

Following a multi-week bench trial, the district court held that (1) the '765 patent was not invalid, (2) it was infringed, (3) MEC's infringement was deliberate and willful, (4) AMS was entitled to an injunction against further infringement, (5) MEC must pay enhanced damages of 1.5 times AMS's proven lost profits and reasonable royalties, and (6) rejected MEC's warranty counterclaims. App. 2. However, the district court limited AMS's recoverable damages to those incurred after the filing date of the lawsuit due to AMS's brief initial failure to mark its patented articles under 35 U.S.C. § 287(a) (1988). App. 2.

On appeal, MEC conceded validity and infringement, but challenged the district court's finding of willfulness, its award of enhanced damages, its alleged rejection of MEC's alleged jury demand and its rejection of MEC's warranty counterclaims. AMS cross-appealed the district court's limitation of its recoverable damages under 35 U.S.C. § 287(a). App. 2. A unanimous panel of the Federal Circuit affirmed the district court's finding of willful infringement, the court's enhancement of the actual damages by 1.5 times, and its rejection of MEC's warranty counterclaims. The Federal Circuit also found MEC's jury demand argument to be without merit. App. 23. On AMS's cross-appeal, the Federal Circuit concluded that the district

court improperly construed 35 U.S.C. § 287(a) by limiting AMS's recoverable damages to those incurred after the suit was filed. App. 2. It reversed and remanded to the district court for a determination of damages commencing from the time AMS began marking and shipping its patented product pursuant to § 287(a). App. 32-33. MEC sought rehearing *en banc* which was denied after full briefing by both parties. App. 117.

In discussing the history of petitioner's willful infringement, the Federal Circuit related the following sequence of events. AMS filed its patent application on December 27, 1984, and the '765 patent issued on July 1, 1986. App. 5. AMS began producing its patented prosthesis prior to issuance of the patent. In May of 1985, MEC personnel saw AMS's product, called the Hydroflex® prosthesis, at an American Urological Association trade show. MEC promptly abandoned its previous packaging configurations after it obtained a sample of the Hydroflex® packaging. MEC then adopted AMS's packaging that was found to infringe the '765 patent. App. 7.

Although MEC's petition asserts that AMS "deliberately" did not give MEC notice of infringement, MEC knew all about the '765 patent essentially from the beginning. As noted by the Court of Appeals, MEC learned of the '765 patent by late July 1986, only a few weeks after the patent issued.[1] App. 7. AMS's patent counsel also telephoned MEC's in-house counsel twice in August 1986, and advised MEC of

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[1] MEC's in-house counsel who learned of the '765 patent was actually employed by Bristol-Myers, of which MEC is a subsidiary, but he was responsible for MEC's patent matters.

the '765 patent. At that time no direct accusation of infringement was made by AMS. App. 7-8. MEC recognized that its product, called Flexi-Flate, infringed the '765 patent so it performed several patent validity searches. These opinions were withheld at trial. App. 8. At the end of August or the beginning of September 1986, MEC's in-house counsel allegedly advised MEC's president, in an undocumented oral opinion, that the '765 patent was invalid for obviousness. In-house counsel also advised that MEC's Flexi-Flate product fell literally within the scope of the '765 patent claims. App. 8.

AMS began fully marking and shipping its product with the '765 patent number about three and one-half months after its issuance. App. 24. Between the dates of issuance and full marking, AMS shipped 1,939 prostheses. App. 24.

Shortly after learning of AMS's '765 patent, MEC began to consider alternative packaging configurations but it did not start selling an alternative pack until after January 1988. App. 8. Even after it developed the alternative product and even though it was fully aware of the '765 patent, MEC continued to ship its remaining inventory of infringing Flexi-Flate throughout the remainder of 1988. App. 8.

While MEC's statement of the case avers that "no facts are disputed" (Pet. 2), the statement significantly omits important facts and distorts others. Once AMS commenced shipping marked products, its marking and shipping were consistent—not merely the shipment of "some or all" products with the patent numbers as alluded by petitioner. Pet. 3. AMS's marking, once initiated, was not random or sporadic as suggested by petitioner's misleading mathematical

statements that 60% of products lacked marking in the first six months after the patent issued and that 25% of the products lacked marking between the patent's issuance and the date of this lawsuit. Pet. 3.

MEC's percentages are all based on the 1,939 prostheses that were originally shipped without marking prior to October 15, 1986. Thereafter, marked products were shipped consistently and the unmarked percentage of the total number of shipped prostheses decreased accordingly. Such percentages have no legal connotation except to cause an incorrect perception that less than all products shipped after October 15, 1986 were marked.

Similarly, petitioner states that AMS did not give it "actual notice of infringement" until the complaint was filed, and that this was done "deliberately." Pet. 3. While petitioner may not have received such a pointed "notice of infringement" that it could file a declaratory judgment action, AMS called the patent to MEC's attention within a month after the patent's issuance. MEC already knew of the patent and yet it continued to infringe and was ultimately adjudicated a willful infringer. MEC is not an unwitting infringer aggrieved by AMS's alleged delay in marking; it is an adjudicated willful infringer who deliberately copied AMS's product, consciously ignored AMS's patent, and now is opportunistically hoping to seize on the initial, short delay in marking to avoid damages. Whether or not MEC received actual notice of infringement from AMS is irrelevant to the Federal Circuit's decision that damages commence when AMS began consistently shipping the marked product.

SUMMARY OF ARGUMENT

1. MEC's petition raises no special or important questions or ramifications, no decisional conflicts, and no serious departures from the accepted and usual course of judicial proceedings that require the exercise of this Court's discretion in granting a writ of certiorari. The decision below applies only to the narrow circumstance of when damages begin to run against a patent infringer in the event of a patentee's initial delay in marking. This is a routine patent case decided on common patent law concepts in which the Federal Circuit adhered to the plain language of 35 U.S.C. § 287(a), which precludes the recovery of damages for patent infringement only for the duration of the patentee's "failure so to mark" patented products with the patent number. Moreover, this interpretation is entirely consistent with the interpretation of two different circuit courts and several district courts which have addressed the exact same issue.

2. There is no violation of any Supreme Court precedent or improper public policy determination in the Federal Circuit's decision. The Supreme Court decisions referred to by MEC generally deal with the policy of the patent laws "in differentiating between ideas subject to patent protection and those freely available." Pet. 10. Nothing in the decision below conflicts with this general policy. The petitioner cites no decisions which pertain to the commencement of damages under 35 U.S.C. § 287(a). The decision below construed § 287(a) in a manner that encourages patent marking promptly upon the issuance of the patent, and in a manner that gives every incentive to mark as soon as possible if there is a "failure so to mark" at the outset. Nothing in the decision below discour-

ages patent marking. To the contrary, petitioner's interpretation affords little incentive to mark patented products if, through inadvertence or unavoidable circumstances, there is an initial and temporary failure to mark. In such an instance, petitioner's interpretation would require actual notice of infringement to commence the recovery of damages throughout the life of the patent, thus offering little reason for a patentee to mark the patented product.

3. The question as to the quantum of damages payable by a patent infringer where there is a delay in patent marking hardly presents an "issue of national importance" as asserted by petitioner. Pet. 19. The very fact that the decision below is entirely consistent with circuit court and district court precedents directly on point further negates any issue of "national importance." Nothing justifies petitioner's assertion that "Innovation is likely to be deterred" by the decision below. Pet. 20. The only deterred "innovation" here is that of a willful infringer desperately attempting to avoid the payment of damages for its deliberate acts.

ARGUMENT: REASONS FOR DENYING WRIT

1. The Petition Presents No Special And Important Reasons Or Extreme Departures From The Accepted And Usual Course Of Judicial Proceedings That Require This Court's Intervention.

MEC's petition should be denied because there are no "special and important reasons" for granting it, as required by Supreme Court Rule 10.1. The Federal Circuit's decision involved no conflict among circuit courts or anything else of an extraordinary or controversial nature. While the petitioner suggests that

some radical statutory construction has been made, and that the Federal Circuit stands in the way of justice because it is the only court with jurisdiction over patent appeals, the reality is that the Federal Circuit was merely applying the same statutory construction that had been previously given to § 287(a) by two different circuits as well as several district courts. The Federal Circuit has not "so far departed from the accepted and usual course of judicial proceedings . . . as to call for an exercise of this Court's power of supervision," as specified in Rule 10.1(a) of this Court. This is a routine case under the patent statute in which the court below followed the plain language of the statute in a manner consistent with ample and unconflicting precedent.

A. Far From Any Conflict Among Circuits Or Departure From Precedent, The Decision Below Merely Construed 35 U.S.C. § 287(a) In The Same Manner As Prior Circuit Court And District Court Decisions.

The Federal Circuit noted that both the Fifth and Sixth Circuits had specifically interpreted § 287(a) to allow damages from the time that actual marking began or from the time of actual notice of infringement, whichever came first. App. 27. The court below initially cited *Wm. Bros Boiler & Manufacturing Co. v. Gibson-Stewart Co.*, 312 F.2d 385-386, 136 USPQ (BNA) 239, 239-240 (6th Cir. 1963), in which the Sixth Circuit held that the patentee was entitled to recover damages from the time of compliance with the marking provisions of the statute, even though the patentee had failed to mark its patented devices for nine months after the date that the patent issued. That

holding was based on the district court's reasoning that:

> Unless and until the patentee marks his patent or serves actual notice upon an alleged infringer he can recover no damages, but . . . nothing in the statute requires marking or notice within any period after issue as a condition for recovery of damages for infringement. . . . The penalty for failure to do either [is] limited to denial of damages for infringement at any time prior to compliance with the requirements of the statute.

Id. at 386, 136 USPQ (BNA) at 240. App. 27.

The court below further pointed out that the Fifth Circuit followed the same reasoning in *Bros, Inc. v. W.E.Grace Manufacturing Co.*, 320 F.2d 594, 599, 138 USPQ (BNA) 357, 359 (5th Cir. 1963). There the court reversed the district court's limitation of damages to the filing date of the lawsuit, and it concluded that recovery of damages should be allowed from the date of marking. App. 27-28.

The Federal Circuit also cited district court decisions reaching the same conclusion with respect to § 287(a). It cited *Briggs v. M&J Diesel Locomotive Filter Corp.*, 228 F. Supp. 26, 63-64, 141 USPQ (BNA) 96, 127 (N.D. Ill.1964), *aff'd*, 342 F.2d 573, 144 USPQ (BNA) 701 (7th Cir.), *cert dismissed*, 382 U.S. 801 (1965), in which the district court held that despite a two year delay in marking, the patentee was entitled to recover damages for infringement that occurred after marking began. App. 28. It noted that in *Mosinee Paper Corp. v. James River Corp.*, 1992 U.S. Dist. LEXIS 2425, 22 USPQ2d (BNA) 1657, 1662, 1992 WL 41690 (E.D. Wis. 1992), the court

determined that the pantentee was entitled to full recovery of damages where the patentee did not begin to mark the product until 1980, prior to infringement, even though the patent in suit issued on August 21, 1979. App. 28.

Another decision discussed by the Federal Circuit at App. 26-27, was *Slimfold Manufacturing Co. v. Kinkead Industries, Inc.*, C.A. No. 1:78-CV-1978-JOF, 1990 WL 512961 (N.D. Ga. May 29, 1990), *aff'd.* 932 F.2d 1453, 18 USPQ2d (BNA) 1842 (Fed. Cir. 1991). In *Slimfold*, the patentee commercialized the invention before the patent issued on May 14, 1974, but did not begin marking the patented product until November 1, 1977. The defendant began infringing in June 1977, the first actual notice of infringement was given in March 1978, and suit was filed in October 1978. The district court held that the patentee was entitled to damages from November 1, 1977, when it began to mark its patented products consistently. App. 26. In reaching this conclusion, the district court in *Slimfold* reasoned that:

> The statute does not require marking within a particular time after issuance of a patent. Both the Fifth and Sixth Circuit Courts of Appeal have so held. *Wm. Bros. Boiler & Mfg. Co. v. Gibson-Stewart Co.*, 312 F.2d 385, 386, 136 USPQ (BNA) 239, 240 (6th Cir. 1963); and *Bros, Inc. v. W.E. Grace Mfg. Co.*, 320 F.2d 594, 599, 138 USPQ (BNA) 357, 359 (5th Cir. 1963): "The Court points out that there is ' . . .nothing in the statute requiring marking or notice within any period after issue as a condition for recovery of damages for infringement. . . .'" Liability for

> infringement begins with marking (or actual notice) whenever that occurs.

On appeal of the *Slimfold* case, the Federal Circuit specifically affirmed the district court's award of damages as of the marking date, although the specific question of the proper interpretation of § 287(a) was not before the court. 932 F.2d at 1456, 1459, 18 USPQ2d (BNA) at 1845, 1847. App. 26-27.

In light of this body of authority, the court below interpreted § 287(a) in a manner entirely consistent with well-established precedent in deciding the patent marking issue. The Federal Circuit's interpretation of § 287(a) was identical to the specific holdings of two circuits as well as district court decisions that were affirmed by two other circuit courts wherein appellants did not even see fit to appeal the marking statute issue. As properly observed by the Federal Circuit, "'MEC fails to adequately distinguish these cases or to convince us that their rationale is unsound." App. 28. Unable to distinguish these cases, the petitioner has simply omitted any reference to them in its petition for certiorari.

The Federal Circuit's holding is entirely consistent with these unconflicting precedents directly on point. Thus, it cannot be said that the decision below "so far departed from the accepted and usual course of judicial proceedings, or sanctioned such a departure by a lower court, as to call for this Court's power of supervision." Supreme Court Rule 10.1(a). Moreover, the commencement of the running of damages against a willful patent infringer when there is a brief delay in marking is hardly "an important question of law which has not been, but should be, settled by this Court" as stated in Supreme Court Rule 10.1(c).

B. The Federal Circuit's Decision Does Not Conflict With The Plain Language Of 35 U.S.C. § 287(a).

Without mentioning the foregoing precedents followed by the Federal Circuit, the petitioner contends that the Federal Circuit's construction of 35 U.S.C. § 287(a) conflicts with the "plain language" of the statute. Pet. 7-10.

Section 287(a) provides as follows:

> Patentees, and persons making or selling any patented article for or under them, may give notice to the public that the same is patented . . . by fixing thereon the word "patent" or the abbreviation "pat.", together with the number of the patent . . . . In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice. Filing of an action for infringement shall constitute such notice.

The court below found no conflict between the above precedents and the plain language of the statute, holding at App. 30 that:

> The plain language of section 287(a) does not provide any time limit by which marking must begin, nor does the legislative history indicate any such limitation. Congress structured the statute so as to tie failure to mark with disability to collect damages, not failure

> to mark *at the time of issuance* with disability to collect damages.

The Federal Circuit noted that the marking statute is permissive,[2] not mandatory ("may give notice to the public"), App. 25, and it simply viewed the phrase "failure so to mark" as describing a temporal state which can be terminated in the passage of time. The brief delay in marking was held not to be a "failure so to mark" once consistent marking began. Under this view of the Federal Circuit and the other courts that have decided this same issue, when a "failure so to mark" no longer exists then the statutory consequence of "no damages" no longer exists. The damages provision of the patent laws, 35 U.S.C. § 284, comes into play when the damages limitation of § 287(a) ceases to apply.

Contrary to this eminently reasonable, straightforward construction supported by the purpose behind

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[2] The change in the marking statute in 1952 from a mandatory requirement to a permissive matter gives indication that a permanent penalty is no longer envisaged for a "failure so to mark" that is only of a temporary duration. The Federal Circuit's decision described the 1952 amendment as follows at App. 25:

> R.S. 4900 [the prior statute] provided that "it shall be the *duty* of all patentees . . . to give sufficient notice to the public that the same is patented . . ." (emphasis added). In 1952, Congress amended R.S. 4900 to become the present section 287(a), changing the language to make marking permissive rather than mandatory, so that a "patentee . . . *may* give notice to the public" by the specified marking. Act of July 19, 1952, ch. 950, § 287, 66 Stat. 813.

The pre-1952 precedents relied on by petitioner MEC below were correctly ruled inapplicable by the Federal Circuit due to the statutory amendment. App. 28-29, n. 15.

the statute and well-established precedent over three decades, the petitioner interprets "failure so to mark" as a state which bears permanent consequences. Once it occurs, petitioner contends, there must be a "penalty paid"—namely, no damages under 35 U.S.C. § 284 until the patentee makes a charge of infringement. Pet. 5.

In support of its position that immutable consequences must necessarily follow even from a temporary failure to mark, petitioner offers only reiterations of its version of the statute. Pet 8-9. Petitioner's assertions completely ignore the permissive language of § 287(a) and that § 287(a) does not establish a time limit in which marking must occur. Petitioner's argument culminates in the contention that the Federal Circuit "wrote into the statute" a non-existent exception. Pet. 8-9. Petitioner even presumes to rewrite § 287(a) in the way that the Federal Circuit supposedly "treated the statute." Pet. 8-9.

No such statutory rewrite was necessary for the court below and the other courts addressing this issue to have decided as they did. As the statute *is written*, marking of the patented product is permissive, and the statutory consequence only occurs "[i]n the event of a failure so to mark." 35 U.S.C. § 287(a). After AMS began consistently shipping marked products, there was no "failure so to mark," the statute was complied with, and there was no basis for any further imposition of the statutory consequences or deferral of damages under 35 U.S.C. § 284. The court below had no need to rewrite § 287(a) to insert an intermediate date for the commencement of damages. The Federal Circuit's decision linking the statutory consequences to the duration of the "failure so to mark"

was in keeping with the plain statutory language, the legislative history and all pertinent precedents.[3]

II. The Decision Below Was Not Inconsistent With The Policies Underlying The Patent Laws Or With Supreme Court Precedent.

Petitioner argues that the decision below is "inconsistent with the policies underlying the patent laws, including those outlined by this Court in its precedent." Pet. 10. This "public policy" argument consists of little more than a series of generalities gleaned from Supreme Court cases having nothing to do with the specific issue of marking under 35 U.S.C. § 287(a). Petitioner has simply failed to point to any inconsistencies between the Federal Circuit's decision and the purpose behind § 287(a).

Petitioner first refers to the "important public policy served by the patent laws in differentiating between ideas subject to patent protection and those freely available," citing six Supreme Court cases. Pet. 10.[4] There is no disagreement with respect to this

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[3] Petitioner's assertions that AMS deliberately withheld a charge of infringement to avoid creating declaratory judgment jurisdiction is irrelevant to the issue. A patentee has no obligation to charge infringement under § 287(a); the reference to notice of infringement therein is applicable only during the period in which there is a "failure so to mark" the patented products.

[4] The cases cited by petitioner are *Bonito Boats, Inc.v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51, 156, 159-62 (1989); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262, 264 (1979); *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480-81 (1974); *Lear, Inc. v. Adkins*, 395 U.S. 653, 656, 668-70 (1969); *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230-31 (1964); *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234, 247 (1964).

broad policy. However, this broad policy does not address the specific issue of whether the court below followed the law in interpreting § 287(a) to allow damages to commence once there was no failure to mark. Indeed, the decision below, by giving an incentive to mark even though there was an initial delay, abets the broad policy of "differentiating between ideas subject to patent protection and those freely available" by providing an incentive to a patentee to mark its product as quickly as possible even where there is a brief delay, thereby providing the earliest possible notice to the public that the product is patented.

The petitioner goes on with further generalities, referring to free exploitation of ideas as the rule and federal patent protection as the exception, citing *Bonito Boats*, 489 U.S. at 151. MEC refers to this Court's statements therein, *Id.* at 162, that patent marking "provides a ready means of discerning the status of the intellectual property embodied in an article of manufacture or design" and that the "public may rely upon the lack of notice in exploiting shapes and designs accessible to all." Pet. 11-12. The quoted language appears in a discussion about administrative problems generated if states were allowed to create patent-like rights in various products in public circulation. These generalities likewise have nothing to do with the commencement of damages under § 287(a). To the extent they are applicable to this case, the Federal Circuit's decision actually augmented the public policy of encouraging the marking of patented products even though there may have been an initial delay. App. 30.

Although the *Bonito Boats* decision was far afield from any interpretation of § 287(a), the petitioner

nonetheless contends that the decision below "conflicts with the Court's reasoning . . . in *Bonito Boats*." Pet. 15. The conflict is unfathomable. *Bonito Boats* addressed what limits the federal patent system placed on the ability of the states to offer substantial statutory protection to utilitarian and design ideas which the patent laws left otherwise unprotected. See 489 U.S. at 143. It held that the states could not create patent-like rights in various products in public circulation. No issue of patent marking or statutory construction of § 287(a) was presented or discussed in *Bonito Boats*, which dealt with a federal-state conflict having no resemblance to the precise issue here.

Petitioner's additional statements that the decision below "conflicts" with *Bonito Boats* (Pet. 15), that it runs "afoul of the law" (Pet. 16), and that it is "inconsistent" with policies "outlined by this Court in its precedent" (Pet. 10) manifest petitioner's misapprehension of the meaning of precedent. In this case, precedent consisted of prior decisions construing § 287(a) in an entirely consistent manner with that of the Federal Circuit, App. 30. None of these cases are even mentioned in the petition.

Contrary to petitioner's assertions, the Federal Circuit gave cogent, sensible public policy reasons for deciding as it did, stating at App. 30:

> Furthermore, allowing recovery of damages from the point of full compliance with the marking statute furthers the policy of encouraging marking to provide notice to the public, even if initial marking after issuance of the patent is delayed. The sooner one complies with the marking requirements, the

> more likely one is to maximize the period of time for recoverable damages. To prevent recovery of damages for failure to immediately mark, however, provides no incentive for a patentee who inadvertently or unavoidably fails to mark initially to mark in the future.

The Federal Circuit, as had the courts previously construing the statute, thus linked the damages preclusion to the duration of the failure to mark. To do otherwise would provide a field day for infringers in cases where a brief delay in marking might occur. Such infringers could enjoy freedom from damages for over 16 years if they could escape detection or otherwise avoid being "notified of the infringement" by the patentee. Under petitioner's interpretation of the statute, that result would prevail even if the patentee began consistent marking after only several months and continued its marking for almost the entire 17 year existence of the patent. This result was repugnant to the Federal Circuit and to all courts that had previously interpreted § 287(a). They were unwilling to construe the statute in a way that would relegate a patentee to such an abyss or to provide such a benefit for opportunistic infringers.

There is no dispute that the purpose of § 287(a) is for the information of the public. Nothing in the Court of Appeals decision conflicts with that purpose. The reasonable interpretation by the court below encourages prompt marking by permitting recovery for the period when the marking provision is complied with, and it also provides an incentive for prompt marking by denying recovery for the period when no marking occurred. An individual who copies an unmarked product in the market is always at risk that the article

being copied is or may become patented. The time and investment bringing that product to market will be lost even when actual notice is given at a later date. Section 287(a) gives no basis for distinguishing actual and constructive notice in this regard. While marking under § 287(a) is no longer mandatory, the decision below encourages a patentee to begin marking as soon as possible, thereby providing the earliest possible notice to the public that the product is patented and maximizing the period of time for recoverable damages. In most instances, this would occur prior to any actual notice which depends on a patentee's ability to locate infringers.

MEC's interpretation would reward infringers who know of a patented product through marking but are able to keep their infringement secret from the patentee, perhaps for many years, by allowing them to avoid damage liability until such time as they can be located and served with actual notice. This was not a policy objective behind §287(a). Petitioner's interpretation to this effect will frustrate the underlying statutory objective of encouraging patentees to mark patented articles promptly.

The marking provision in § 287(a) is clearly related to the recovery of damages. The incentives and benefits of marking provided in § 287(a) logically are damage oriented. Section 287(a) is an exception to the general damage rule of § 284 and acts as a *limitation* on damages, not a "penalty." However, it is a limitation that applies only until consistent marking is accomplished or actual notice is given.

Petitioner further debases the meaning of precedent by citing three Supreme Court cases for propositions such as "substantially all products must be marked"

(Pet. 12), *Providence Rubber Co. v. Goodyear*, 9 Wall. (76 U.S.) 788, 801 (1870); patentees "cannot recover damages" unless there is marking or notice of infringement (Pet. 12-13), *Dunlap v. Schofield*, 152 U.S. 244, 247-48 (1894); or that a patentee has a "duty" to mark (Pet. 13), *Wine Ry. Appliance Co. v. Enterprise Ry. Equip. Co.*, 297 U.S. 387, 393 (1936).[5] All of these cases were decided under predecessor statutes which, as noted *supra*, did place a mandatory "duty" on patentees to mark. These cases are not precedent under § 287(a), which became law by the 1952 amendment that abrogated any "duty" to mark. The court below was correct in not applying the pre-1952 statute and related precedents.

After stating that the marking statute was meant to minimize the possibility that the "public might innocently believe a patented article can be copied" (Pet. 13), petitioner attempts to cloak itself in such innocence by pointing to respondent's brief delay in marking and unwillingness to trigger a declaratory judgment action by giving notice of infringement. Pet. 14. Petitioner can scarcely don such a mask of innocence, for it was apprised of the patent by respondent in the month following issuance and so flagrantly persisted in its infringement that petitioner was found guilty of willful infringement.

Petitioner then contends that there is an "unjustified inconsistency" in the Federal Circuit's decision

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[5] The *Wine Ry.* case actually addressed whether a patentee who had *never* manufactured or vended an article under the infringed patent was barred from recovering damages when no notice was given to the accused infringer prior to the patentee's filing a counterclaim for infringement. The decision thus dealt with different facts under a different statute.

in that a patent owner that continually distributes 25% of its patented products unmarked is treated differently from the patent owner that initially fails to mark its product and then consistently marks the product. Pet. 14-15. At some point after marking is begun consistently, it can be said that 25% was unmarked—but it cannot be said that the "harm to the public is the same." Pet. 15. In the instance where consistent marking is begun, the point where 25% remains unmarked is only a momentary point, after which the unmarked percentage drastically diminishes as further marked product is shipped, with the ultimate likelihood that 100% of the product in the field will be marked. The Federal Circuit's decision recognizes this reality in treating the situations differently. Petitioner's assertions that the Court of Appeals reached a "curious outcome" is based solely on flawed mathematics. Pet. 15.

This same flawed mathematics pervades petitioner's argument that the Federal Circuit's decision will bring about thousands of unmarked products—so-called hidden mines in the sea of ideas. Pet. 16. The decision below will effect an opposite result. The patentee has no reason to delay marking when a patent issues; when a delay occurs, it is normally "inadvertently or unavoidably," caused, as noted by the court below. App. 30. The Federal Circuit's decision has nothing to do with encouraging a patentee to delay marking. But it does encourage the patentee to minimize the so-called undetonated mines by marking consistently as soon as possible and continuing to mark so that soon there will be no unmarked products in the field. Absent this incentive inherent in the Court of Appeals decision, the patentee's initial delay in marking would

consign the patentee for the life of the patent to a requirement to give notice of infringement before recovery of damages can commence. Under such a state of affairs, there would be less incentive to mark because all would be lost by the temporary inadvertence at the outset. There is absolutely no merit to petitioner's argument that the decision below "will improperly impede the use of ideas in public circulation by removing a clear demarcation between ideas in the public domain and those subject to the private rights of patent owners." Pet. 16.

Similarly, the decision below did not wrongly assume that damages for infringement is the "only incentive" a patentee has to mark its product. Pet. 17. Nothing in the Federal Circuit's decision refers to the damages aspect as the "only incentive" for prompt marking. The decision does provide a compelling incentive to mark, however, one that is far more quantifiable in effect than petitioner's generalized suggestion that marking "serves to deter potential infringers." Pet. 17. Indeed, petitioner's generalized suggestion is belied by its own conduct. AMS's subsequent consistent marking and petitioner's knowledge of AMS's patent did nothing to deter petitioner from its continued willful infringement in this case.

It is hardly correct to say that under the Federal Circuit's decision "patent owners need not concern themselves with marking immediately" or that "[f]ew patent owners will indulge in efforts to immediately mark." Pet. 17. The Federal Circuit's decision calls out for marking as soon as possible in order to commence the right to obtain damages. It does not encourage a delay in marking, for any delay works against the patentee under the decision below.

The Federal Circuit's decision is not a "significant departure from Supreme Court precedent" (Pet. 18) and is not "at odds with the strong federal policy of protecting the public's right to use freely circulated *unpatented* ideas" (Pet. 19). This case has nothing to do with "*unpatented* ideas" and violates no Supreme Court precedent no matter how loosely precedent is defined. The Supreme Court cases cited by petitioner amount to little more than name-dropping of important cases; the cited cases either applied to the pre-1952 marking statute or to issues of far different, far greater significance than the issue of when patent infringement damages should commence to run against a willful infringer when there is a brief delay in marking. The truly applicable precedents construing § 287(a) after it became law in 1952, *supra*, have been inexcusably omitted from the petition. As a result, the petition presents an unbalanced, incomplete statement of both the law and the underlying policy considerations.

III. The Petition Does Not Address An Issue Of National Importance.

The decision below simply interpreted 35 U.S.C. § 287(a) in the same way it had been interpreted by two different circuits and several district courts. It is a deception, therefore, for petitioner to assert that this Court must intervene because of the Federal Circuit's currently established "exclusive jurisdiction" over patent appeals. Pet. 20. While there is no longer a possibility of conflict among circuits, the petition conveniently overlooks that the Federal Circuit's decision was in complete accord with prior circuit court and district court decisions. And the decision was rendered by a court having special expertise in patent

issues. Such a state of affairs, which relates solely to the quantum of damages payable by infringers in situations where there is a brief delay in patent marking scarcely suggests an "issue of national importance." Pet. 19.

The court below did not engage in "eviscerating the penalty designed by Congress" (Pet. 19), but merely interpreted § 287(a) in a manner consistent with its plain language, the policy behind the statute and the precedents directly on point. The interpretation struck an even-handed balance between patentee, infringer and the purpose behind the statute. It served to encourage marking as soon as possible after patent issuance if there was an initial delay in marking. Nothing in the decision discourages marking, nor justifies petitioner's wildly exaggerated assertion that: "Innovation is likely to be deterred" by reason of the decision below. Pet. 20.

CONCLUSION

For the reasons stated, the petition for a writ of certiorari should be denied.

Respectfully Submitted,

RUDOLF E. HUTZ
Counsel of Record
JAMES M. MULLIGAN, JR.
GEORGE PAZUNIAK
R. ERIC HUTZ
CONNOLLY, BOVE, LODGE & HUTZ
1220 Market Street
P.O. Box 2207
Wilmington, Delaware 19899
(302) 658-9141

Attorneys for Respondent
American Medical Systems, Inc.

April 7, 1994

Supreme Court, U.S.
FILED
APR 22 1994
OFFICE OF THE CLERK

No. 93-1431

IN THE

Supreme Court of the United States

OCTOBER TERM, 1993

MEDICAL ENGINEERING CORPORATION,
Petitioner,

v.

AMERICAN MEDICAL SYSTEMS, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITIONER'S REPLY BRIEF

MARK T. BANNER
Counsel of Record
JERRY A. RIEDINGER
MARC S. COOPERMAN
A. BLAIR HUGHES
ALLEGRETTI & WITCOFF, LTD.
10 South Wacker Drive
Suite 3000
Chicago, Illinois 60606
(312) 715-1000
Counsel for Petitioner

April 22, 1994

Midwest Law Printing Co., Chicago 60611, (312) 321-0220

RULE 29.1 LISTING

Petitioner, Medical Engineering Corporation, previously included a Rule 28.1 listing in its "Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit" at page ii. The listing is currently accurate and no amendments are required.

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PETITIONER'S REPLY BRIEF

I. THE DISPUTED QUESTION PRESENTED IS WHETHER THE FEDERAL CIRCUIT IMPROPERLY INTERPRETED THE TERM "FAILURE SO TO MARK" AS IT IS USED IN 35 U.S.C. §287(a).

This case presents a straightforward, but significant, issue of patent law: whether a patent holder—having failed to mark a substantial number of articles distributed to the public—may claim damages for infringement from the date that it belatedly begins marking or, having initially failed to mark, may claim damages for infringement only from the date that it provides notice of infringement to the infringer. As stated in the petition, our view is that,

once a failure to mark has occurred, Section 287(a) of Title 35 bars recovery of damages prior to the time of actual notice of infringement. By holding to the contrary, the Federal Circuit, charged with deciding all patent appeals, has distorted the statutory scheme in a manner that only this Court can correct.

The Brief in Opposition, while defending the decision below, fails to demonstrate either that it is correct or that (if incorrect) it is unimportant. Its main point on the merits—that a failure to mark leads to a loss of damages only for the period of the failure—is hardly the most natural reading of the statutory language and would make it far more difficult for the public to know whether unmarked articles were covered by a patent or not. And its principal argument about lack of importance—that there is no conflict among the circuits on this issue—is of little relevance, given the fact that the Federal Circuit is the sole court of appeals with jurisdiction over this issue. Plenary review by this Court, therefore, is warranted.

The purpose of the patent marking statute is to "prevent innocent infringement" and to protect the public from "deception by unmarked patented articles." *Wine Ry. Appliance Co. v. Enterprise Ry. Equip. Co.*, 297 U.S. 397, 396-398 (1936). The marking statute (35 U.S.C. §287(a)) thus provides that a patentee may protect the public against deception caused by the public dissemination of unmarked patented articles by giving "notice to the public that the same is patented either by fixing thereon the word 'patent' . . . together with the number of the patent." 35 U.S.C. §287(a) (1990). The statute further states:

> In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except upon proof that the infringer was notified of infringement and continued to infringe thereafter . . . .

Id.

Although AMS argues that a patentee may fail to mark its product and yet later claim damages without giving actual notice, it cannot satisfactorily reconcile that reading with the language of Section 287(a). Once a patentee has distributed more than an insignificant number of unmarked patented articles, it has "fail[ed] so to mark" under the terms of the Act. At that point, Section 287(a) expressly requires the patentee to use the second affirmative method of notice—actual notice of infringement to an infringer—before the patentee is entitled to any damages for the infringement. MEC's interpretation of Section 287(a) finds support in the literal language of the statute, in case law[1] and in the public policy reflected in the patent laws.

AMS never comes to grips with the serious harm caused by the public distribution of unmarked yet patented articles. The patent laws serve the important public policy of delineating between public and private property. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51, 156, 159-62 (1989). Implicit in the patent laws is the concept that "free exploitation of ideas will be the rule, to which the protection of a federal patent is the exception." *Id.* at 151. This policy is embodied in Section 287(a), which provides a mechanism for the patentee to

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[1] Cases supporting MEC's position include: *The Providence Rubber Co. v. Goodyear*, 76 U.S. (9 Wall.) 788, 801 (1870); *Crier v. Innes*, 170 F. 324, 326 (2d Cir. 1909); *Maxwell v. J. Baker, Inc.*, 805 F. Supp. 728, 733 (D. Minn. 1992); *In re Yarn Processing Patent Validity Litigation*, 602 F. Supp. 159, 168-69 (W.D.N.C. 1984); *Gordon v. Easy Washing Machine Corp.*, 39 F. Supp. 202, 203 (N.D.N.Y. 1941); *Hazeltine Corp. v. Radio Corp. of Am.*, 20 F. Supp. 668, 671 (S.D.N.Y. 1937); *Matthews & Willard Mfg. v. National Brass & Iron Works*, 71 F. 518, 518 (C.D. Pa. 1895). The cases decided before the 1952 amendment to Section 287(a) were wrongly dismissed by the Federal Circuit because it mistakenly attributed legislative significance to an insignificant language clarification.

give notice to the world that the exception to the rule—protection of an idea by federal patent—applies to an article placed in the stream of commerce.

The patent marking statute exists to protect the public from innocently infringing on the patent rights of another by encouraging the patentee—by barring or limiting a patentee's entitlement to infringement damages—to give the public affirmative notice of its patent rights.[2] *Wine Ry. Appliance Co.*, 297 U.S. at 295. To protect the public from innocent infringement, Section 287(a) places a small burden on the patentee to mark its patent number on substantially all patented articles and an equally small burden on the public to examine articles for a patent number to determine if the ideas embodied by the article are public property or protected by federal patent. Clearly, unmarked yet patented articles placed in the stream of commerce can mislead any member of the public into believing that the ideas embodied in the unmarked article are freely exploitable. A patentee who fails to notify the public of its patent rights by substantially marking its patented articles with the patent number thereafter has the small burden of monitoring the marketplace and giving infringers actual notice of their infringement. Infringement that continues after actual notice of infringement is no longer innocent, and Section 287(a) allows a patentee to receive damages.[3]

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[2] Innocent infringement occurs when a member of the public examines a patented but unmarked article and is led by the article's lack of patent notice to believe that the ideas embodied in the article are freely available to the public, and thereafter exploits the ideas commercially.

[3] AMS is mistaken that the question presented by this petition is unimportant because MEC is not an innocent infringer. The

(Footnote continued on following page)

AMS suggested examples in its Opposition Brief of why the District Court's and MEC's interpretation of Section 287(a) is supposedly unfair. Most of AMS' arguments focus on why MEC's interpretation of Section 287(a) is unfair to the patentee. *See e.g.*, Opp. 18-22. However, AMS' arguments ignore the policy of the statute which is to protect the public—not the patentee.[4] AMS' arguments all place the burden on the public to spend years monitoring commercial articles to determine if, eventually, the article is marked with a patent number. Such a burden has a chilling effect on the right to "rely upon the lack of notice in exploiting shapes and designs accessible to all." *Bonito Boats*, 489 U.S. at 162.

AMS' position and the position adopted by the Federal Circuit in the decision below is that the plain language

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[3] *continued*
marking statute applies to limit damages for any infringement—innocent or not—occurring prior to receiving actual notice of infringement. Besides, MEC sold infringing articles before AMS marked its patented articles and did not receive actual notice of infringement until sued by AMS for patent infringement. (App. 7).

[4] In the very recent case of *Amsted Indus., Inc. v. Buckeye Steel Castings Co.*, No. 93-1333, -1339 (Fed. Cir. Apr. 18, 1994), the Federal Circuit reaffirmed the important public policy of the patent marking statute as fulfilling "the policy goal of notifying the public concerning the patent status of items in commerce." *Id.* slip op. at 15. The court said that the purpose of the marking statute was to encourage the patentee "to give notice to the public" of the patent. *Id.* The decision below for which certiorari is sought severely undermines that public policy goal by removing the penalty clearly imposed by Congress for a "failure so to mark" a patented article. The only difference between *Amsted* and the present case is that in *Amsted*, the patented article was never marked. In the present case the patent owner initially failed to mark a substantial number of patented articles distributed in commerce, and thereafter consistently marked the product. This incongruity in the interpretation of the patent marking statute can only be cured if this petition is accepted.

of Section 287(a) allows a patentee to obtain damages for infringement from the date the patent number is placed on all patented articles distributed in commerce regardless of the number of and length of time that unmarked patented articles had been placed in the stream of commerce. (App. 30-31). The basis for the decision below and AMS' arguments in support of its position are contrary to the literal statutory language, the legislative history, and to the intent of the marking statute which is to protect the public from innocent patent infringement. *Wine Ry. Appliance Co.*, 297 U.S. at 395.

The Federal Circuit summarized its interpretation of the marking statute as follows:

> we construe section 287(a) to preclude recovery of damages only for infringement for any time *prior to* compliance with the marking or actual notice requirements of the statute. Therefore, a delay between issuance of the patent and compliance with the marking provisions of section 287(a) will not prevent recovery of damages *after* the date that marking has begun.

(App. 31) (Emphasis added).

The highlighted words identify how the Federal Circuit rewrote the statute. The Federal Circuit distinguished activity occurring "prior to" from that occurring "after" marking, a distinction wholly absent from the statute's terms. The statute does, however, expressly distinguish between events occurring before "the infringer was notified" of the infringement, and events occurring thereafter. Once a failure to mark has occurred, the statute expresses a straightforward prohibition on damages by saying "*no* damages shall be recovered by the patentee in *any* action for infringement, except on proof that the infringer was notified on the infringement and continued to infringe there-

after, in which event damages may be recovered only for infringement occurring after such notice." (Emphasis added).

The Congressional inclusion of an express distinction between events before and after a notice of infringement shows that Congress was perfectly capable of distinguishing between events before and after marking, if it had intended to do so. Instead, Congress simply stated that, once there had been a "failure so to mark," "no damages shall be recovered" except, of course, upon actual notice of infringement. "No" damages means "none." It does not mean no damages until "after the date that marking has begun." The Federal Circuit nevertheless implied the very distinction into the statute that Congress could have made, but did not.

In its Opposition Brief, AMS emphasizes that patent marking is permissive and not mandatory and cites a portion of the decision below in which the Federal Circuit concluded that the change of a single word in the marking statute by the 1952 amendment to the patent code changed marking from a mandatory to a permissive act. Supposedly that single change extinguished any precedent provided by case law decided prior to 1952. (App. 28-30). Whether the statute permits marking or creates a duty to mark is, however, irrelevant. This case addresses the consequences that flow from a failure to mark, and in both the pre-and post 1952 statutes, the consequence was the same: "no damages shall be recovered" except upon actual notice of infringement. Such a result also follows from the meager legislative history of the 1952 Act which characterized the amendment to Section 287(a) as a "reorganization in language to clarify." S. Rep. No. 1979, 82d Cong. 2d Sess. 2397, 2403 (1952). If Congress had actually intended to change the consequences of a failure to mark

when the 1952 Act was written, it would not have done so by the decidedly oblique method of deleting the word "duty" without comment.

AMS argues that the public is aided by the decision below because it encourages the patentee to mark its patent number on a patented article even after distributing unmarked patented articles in commerce. Yet the decision below allows a patentee to flood the market with unmarked patented articles and still obtain damages from an infringer—innocent or not—as soon as the patent number is placed on a single patented article. For example, consider a patentee who sells ten thousand patented but unmarked articles over a five year period and then begins marking with the ten thousand and first. The decision below holds that once the patentee marks the patent number on the ten thousand and first patented article, the presence of ten thousand unmarked patented articles still existing in the stream of commerce to mislead the public has no effect and "the delay between issuance of the patent and compliance with the marking provisions of section 287(a) will not prevent recovery of damages . . . ." (App. 31). This is precisely the public injury that Section 287(a) is intended to prevent.

The decision below is flawed because it ignores the impact on the public—the very class that the statute is intended to protect. The decision improperly burdens the public to monitor the marketplace to verify that an idea embodied in an article is not patented while simultaneously eliminating the patentee's burden to immediately and thoroughly inform the public of its patent rights.

II. THE PROPER INTERPRETATION OF THE PATENT MARKING STATUTE IS A QUESTION OF GREAT PUBLIC IMPORTANCE.

The question presented concerns the proper interpretation of a statutory provision intended by Congress to protect the public. Because the decision below was rendered by the Federal Circuit, it is binding on all District Courts.

The Federal Circuit has exclusive jurisdiction over all appeals from District Courts involving patent law issues. 28 U.S.C. §1295 (1990). That exclusive patent jurisdiction makes its rulings of special national importance. *See Cardinal Chemical Co. v. Morton Intern., Inc.*, 113 S.Ct. 1967, 1971 (1993) (concluding that Federal Circuit's exclusive jurisdiction over an appeal involving a patent issue made the question presented to the Court "a matter of special importance to the entire nation"). It is, therefore, especially important for the Court to consider this petition.

A correct resolution of the question presented is vital to patent owners and the public alike. The plain language of Section 287(a) places the burden on patentees to differentiate publicly available ideas from ideas protected by a federal patent. The decision below has shifted that burden to the public, which must now continuously monitor articles in commerce for a change in patent number marking. Review of the question presented is critical to determine if the decision below properly allocated the statutory burdens.

CONCLUSION

For the reasons stated, the Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

MARK T. BANNER
Counsel of Record
JERRY A. RIEDINGER
MARC S. COOPERMAN
A. BLAIR HUGHES
ALLEGRETTI & WITCOFF, LTD.
10 South Wacker Drive
Suite 3000
Chicago, Illinois 60606
(312) 715-1000
Counsel for Petitioner

April 22, 1994